# **New Mexico Harm Reduction Laws**

#### Harm Reduction Act 24-2C-1 to 24-2C-6 NMSA 1978

24-2C-1. Short title.

Sections 1 through 6 [24-2C-1] to 24-2C-6 NMSA 1978] of this act may be cited as the "Harm Reduction Act".

**History:** Laws 1997, ch. 256, § 1.

#### 24-2C-2. Purpose.

The purpose of the Harm Reduction Act is to:

- A. prevent the transmission of the human immunodeficiency virus, hepatitis B and C viruses and other blood-borne diseases; and
- B. encourage intravenous drug users to seek substance abuse treatment and ensure that participants receive individual counseling and education to decrease the risk of transmission of blood-borne diseases.

History: Laws 1997, ch. 256, § 2.

#### 24-2C-3. Definitions.

As used in the Harm Reduction Act:

- A. "department" means the department of health;
- B. "participant" or "client" means an intravenous drug user who exchanges a used hypodermic syringe, needle or other object used to inject controlled substances or controlled substance analogs into the human body for a sterile hypodermic syringe and needle in compliance with the procedures of the program; and
- C. "program" means a harm reduction program for the purpose of sterile hypodermic syringe and needle exchange.

**History:** Laws 1997, ch. 256, § 3.

#### 24-2C-4. Program created; department responsibilities.

- A. The department shall:
- (1) establish and administer a harm reduction program for the purpose of sterile hypodermic syringe and needle exchange;
- (2) compile data to assist in planning and evaluating efforts to combat the spread of blood-borne diseases; and
- (3) make an annual report, including legislative recommendations, to the legislative health and human services committee by October 1 each year.
- B. Within thirty days of the effective date of the Harm Reduction Act, the department shall appoint an advisory committee, to include representation from:
- (1) the office of the attorney general;
- (2) the New Mexico state police division of the department of public safety;
- (3) the human immunodeficiency virus sexually transmitted disease bureau of the department;
- (4) the director of the epidemiology division of the department or his designee;

- (5) a medical officer of the public health division of the department; and
- (6) other persons or representatives as chosen by the secretary of health to ensure a thorough and unbiased evaluation of the program established under the Harm Reduction Act.
- C. The advisory committee shall:
- (1) develop policies and procedures for evaluation of the harm reduction program;
- (2) develop criteria for data collection and program evaluation; and
- (3) meet as necessary to analyze data and monitor and produce a report on the harm reduction program.
- D. The department may contract with private providers to operate the program.

History: Laws 1997, ch. 256, § 4.

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- D. The department may contract with private providers to operate the program.

History: Laws 1997, ch. 256, § 4.

# 24-2C-5. Program.

The program shall provide:

- A. sterile hypodermic syringes and needles in exchange for used hypodermic syringes, needles or other objects used to inject controlled substances or controlled substance analogs into the human body;
- B. education to participants on the transmission of the human immunodeficiency virus, hepatitis B and C and prevention measures; and
- C. referral to substance abuse treatment services for participants.

History: Laws 1997, ch. 256, § 5.

24-2C-6. Immunity from criminal liability.

Exchange or possession of hypodermic syringes and needles in compliance with the procedures of the program shall not constitute a violation of the Controlled Substances Act [Chapter 30, Article 31 NMSA 1978] for a participant in the program, an employee of the department administering the program or a private provider whom the department contracts with to operate the program.

History: Laws 1997, ch. 256, § 6.

#### Controlled Substance Act 30-31-25.1 NMSA 1978

- 30-31-25.1. Possession, delivery or manufacture of drug paraphernalia prohibited; exceptions. A. It is unlawful for a person to use or possess with intent to use drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale or otherwise introduce into the human body a controlled substance in violation of the Controlled Substances Act. The provisions of this subsection do not apply to a person who is in possession of hypodermic syringes or needles at the time he is directly and immediately engaged in a harm reduction program, as provided in the Harm Reduction Act [24-2C-1 NMSA 1978].
- B. It is unlawful for a person to deliver, possess with intent to deliver or manufacture with the intent to deliver drug paraphernalia with knowledge, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale or otherwise introduce into the human body a controlled substance in violation of the Controlled Substances Act. The provisions of this subsection do not apply to:
- (1) department of health employees or their designees while they are directly and immediately engaged in activities related to the harm reduction program authorized by the Harm Reduction Act; or
- (2) the sale or distribution of hypodermic syringes and needles by pharmacists licensed pursuant to the Pharmacy Act [61-11-1 NMSA 1978]
- C. A person who violates this section with respect to Subsection A of this section is guilty of a misdemeanor and upon conviction shall be punished by a fine of not less than fifty dollars (\$50.00) nor more than one hundred dollars (\$100) or by imprisonment for a definite term less than one year, or both. A person who violates this section with respect to Subsection B of this section is guilty of a misdemeanor.
- D. A person eighteen years of age or over who violates the provisions of Subsection B of this section by delivering drug paraphernalia to a person under eighteen years of age and who is at least three years his junior is guilty of a fourth degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978.

**History:** 1978 Comp., § 30-31-25.1, enacted by Laws 1981, ch. 31, § 2; 1997, ch. 256, § 7; 2001, ch. 189, § 1.

#### 24-1-20 NMSA 1978 Records confidential.

- A. The files and records of the department giving identifying information about individuals who have received or are receiving from the department treatment, diagnostic services or preventive care for diseases, disabilities or physical injuries, are confidential and are not open to inspection except where permitted by rule of the department, as provided in Subsection C of this section and to the secretary of health and environment [secretary of health] or to an employee of the health and environment department [department of health] authorized by the secretary to obtain such information, but the information shall only be revealed for use in connection with a governmental function of the secretary or the authorized employee. Both the secretary and the employees are subject to the penalty contained in Subsection F of this section if they release or use the information in violation of this section.
- B. All information voluntarily provided to the director or his agent in connection with studies designated by him as medical research and approved by the secretary of health and environment [secretary of health], either conducted by or under the authority of the director for the purpose of reducing the morbidity or mortality from any cause or condition of health, is confidential and shall be used only for the purposes of medical research. The information shall not be admissible as evidence in any action of any kind in any court or before any administrative proceeding or other action.
- C. The human services department and the office of the state long-term care ombudsman shall have prompt access to all files and records in the possession of the licensing and certification bureau of the department that are related to any health facility investigation. Officers and employees of those agencies with such access are subject to the penalty in Subsection F of this section if they release or use the information in violation of this section.
- D. The files and records of the department are subject to subpoena for use in any pending cause in any administrative proceeding or in any of the courts of the state, unless otherwise provided by law.
- E. No person supplying information to the department for use in a research project or any cooperating person in a research project shall be subject to any action for damages or other relief as a result of that activity.
- F. Any person who discloses confidential information in violation of this section is guilty of a petty misdemeanor.

**History:** 1953 Comp., § 12-34-20, enacted by Laws 1973, ch. 359, § 20; 1975, ch. 324, § 1; 1977, ch. 253, § 41; 1990, ch. 105, § 3.

#### 24-1-3 NMSA 1978 Powers and authority of department.

The department has authority to:

- A. receive such grants, subsidies, donations, allotments or bequests as may be offered to the state by the federal government or any department thereof or by any public or private foundation or individuals;
- B. supervise the health and hygiene of the people of the state;
- C. investigate, control and abate the causes of disease, especially epidemics, sources of mortality and other conditions of public health;
- D. establish, maintain and enforce isolation and quarantine;

- E. close any public place and forbid gatherings of people when necessary for the protection of the public health;
- F. establish programs and adopt rules to prevent infant mortality, birth defects and morbidity;
- G. prescribe the duties of public health nurses and school nurses;
- H. provide educational programs and disseminate information on public health;
- I. maintain and enforce rules for the licensure of health facilities;
- J. bring action in court for the enforcement of health laws and rules and orders issued by the department;
- K. enter into agreements with other states to carry out the powers and duties of the department;
- L. cooperate and enter into contracts or agreements with the federal government or any other person to carry out the powers and duties of the department;
- M. maintain and enforce rules for the control of communicable diseases deemed to be dangerous to public health;
- N. maintain and enforce rules for immunization against diseases deemed to be dangerous to the public health;
- O. maintain and enforce such rules as may be necessary to carry out the provisions of the Public Health Act and to publish the rules;
- P. supervise state public health activities, operate a dental public health program and operate state laboratories for the investigation of public health matters;
- Q. sue and, with the consent of the legislature, be sued;
- R. regulate the practice of midwifery;
- S. administer legislation enacted pursuant to Title VI of the Public Health Service Act, as amended and supplemented;
- T. inspect such premises or vehicles as necessary to ascertain the existence or nonexistence of conditions dangerous to public health or safety;
- U. request and inspect, while maintaining federal and state confidentiality requirements, copies of:
- (1) medical and clinical records reasonably required for the department's quality assurance and quality improvement activities; and
- (2) all medical and clinical records pertaining to the individual whose death is the subject of inquiry by the department's mortality review activities; and
- V. do all other things necessary to carry out its duties.

**History:** 1953 Comp., § 12-34-3, enacted by Laws 1973, ch. 359, § 3; 1975, ch. 183, § 2; 2001, ch. 119, § 2.

# **New Mexico Harm Reduction Regulations**

**NMAC 7.4.6** 

TITLE 7 HEALTH

**CHAPTER 4 DISEASE CONTROL** 

PART 6 REQUIREMENTS GOVERNING THE HARM REDUCTION/SYRINGE EXCHANGE

**PROGRAM** 

**7.4.6.1 ISSUING AGENCY:** Department of Health, Public Health Division, Bureau of Infectious Diseases, 1190 St. Francis Drive, P.O. Box 26110, Santa Fe, New Mexico 87502-6110.

[9/30/99; Recompiled 10/31/01]

**7.4.6.2 SCOPE:** These regulations govern the creation and operation of harm reduction programs for the purpose of sterile hypodermic syringe and needle exchange pursuant to the Harm Reduction Act (Section 24-2C-1 et seq. NMSA 1978).

[9/30/99; Recompiled 10/31/01]

**7.4.6.3 STATUTORY AUTHORITY:** New Mexico Harm Reduction Act (Section 24-2C-1 et seq. NMSA 1978), the Public Health Act (Section 24-1-3 NMSA 1978) and the Controlled Substances Act (Section 30-31-25.1A NMSA 1978).

[9/30/99; Recompiled 10/31/01]

**7.4.6.4 DURATION:** Permanent.

[9/30/99; Recompiled 10/31/01]

**7.4.6.5 EFFECTIVE DATE:** September 30, 1999, unless a later date is cited at the end of a Section or Paragraph.

[9/30/99; Recompiled 10/31/01]

[Compiler's note: The words *or paragraph*, above, are no longer applicable. Later dates are now cited only at the end of sections, in the history notes appearing in brackets.]

**7.4.6.6 OBJECTIVE:** Regulations are required by the Harm Reduction Act to establish and regulate harm reduction programs that include syringe exchange programs as a component to reduce the transmission of blood borne viral infections among injection drug users, to encourage intravenous drug users to seek substance abuse treatment and ensure that participants in DOH authorized syringe exchange programs receive individual counseling and education to decrease the risk of transmission of blood-borne diseases, in accordance with Section 24-2C-1 NMSA 1978.

[9/30/99; Recompiled 10/31/01]

#### **7.4.6.7 DEFINITIONS:** as used in these regulations:

- A. "Blood borne pathogens" means hepatitis B, hepatitis C, the human immunodeficiency virus and any other blood borne diseases as may be specified by the department of health.
- B. "Biohazardous waste container" is a container that is certified by the occupational safety and health administration for the disposal of used or contaminated hypodermic needles and syringes.
- C. "Community health services provider" includes agencies and organizations that provide health care services and prevention services to the citizens of the state of New Mexico, either through public or private funding. Examples include the department of health district health offices, private substance use treatment centers, and community-based organizations that provide outreach to injection drug users.
- D. "Department of health (DOH)" refers to the New Mexico department of health. Department of health agencies that are involved in the regulation and evaluation of syringe exchange programs include the public health division (infectious disease bureau and the office of epidemiology), the behavioral health services division and the division of health improvement.
- E. "Fixed syringe exchange cite" is a building in which a department of health authorized syringe exchange program conducts syringe exchange sessions in accordance with the Harm Reduction Act and these regulations.

- F. "Harm Reduction Act" is Section 24-2C-1 et seq. NMSA 1978.
- G. "Harm reduction program" is a program that includes a department of health authorized syringe exchange program as a component and includes public health education activities for injection drug users. These activities must include, but are not limited to, education about the risks of needle sharing behavior, safer drug injection techniques, individual counseling encouraging safer sexual practices, safe disposal of contaminated syringes and education to decrease the risk of blood-borne diseases, and substance abuse treatment. Community health service providers that conduct department of health authorized syringe exchange programs are required to incorporate those activities into a comprehensive harm reduction program.
- H. "Injection drug user" is a person who uses hypodermic syringes and needles to inject drugs (other than legally prescribed medications such as insulin, erythropoietin and testosterone) into their body.
- I. "Medical director" is the medical director of the infectious disease bureau of the department of health or a physician designated by the secretary of the department of health.
- J. "Mobile syringe exchange site" is a vehicle in which a syringe exchange program conducts syringe exchange sessions at various approved locations on department of health approved time schedules.
- K. "Needle stick accident" is an event in which a syringe exchange program staff member, volunteer or client is inadvertently or intentionally stuck with a used contaminated hypodermic needle. It does not include the intentional injection of controlled or illegal drugs by injection drug users.
- L. "Roving syringe exchange" is a syringe exchange session conducted by syringe exchange program staff traveling on foot during department of health approved time schedules at various approved locations.
- M. "Syringe exchange program" is a program implemented by a community health services provider that is authorized by the department of health to exchange sterile hypodermic syringes and needles with Injection drug users who are enrolled in the department of health's authorized syringe exchange program.
- N. "Syringe exchange program client" is an injection drug user who is enrolled in a department of health authorized syringe exchange and harm reduction program for the purpose of participating in harm reduction program activities and for exchanging syringes.
- O. "Syringe exchange program identification number" is a unique identification number that is assigned by the department of health to the syringe exchange program client for the purposes of assuring the identity of the client, for tracking department of health authorized syringe exchange program utilization and for evaluating syringe exchange program outcomes.

- P. "Syringe exchange program membership card" is a plastic-laminated, wallet-sized card issued by the department of health through its authorized agents to the syringe exchange program client at the time of enrollment that entitles the injection drug user client to participate in the department of health authorized syringe exchange program.
- Q. "Syringe exchange program provider" is a community health service provider that is authorized by the department of health pursuant to a valid agreement to exchange sterile hypodermic syringes and needles as part of a harm reduction program.
- R. "Syringe exchange program staff" are employees of a community health services provider that participates in the activities of a currently authorized department of health syringe exchange program who agree to abide by the requirements of the Harm Reduction Act and these regulations.
- S. "Syringe exchange program supervisor" is a bona fide employee of a community health services provider that is responsible for directing the activities of a currently authorized department of health syringe exchange program and who agrees to abide by the requirements of the Harm Reduction Act.
- T. "Syringe exchange program volunteer" is a person who participates in the activities of a currently authorized department of health syringe exchange and harm reduction program as a volunteer worker who agrees to abide by the requirements of the Harm Reduction Act and these regulations.
- U. "Syringe exchange session" is a department of health approved scheduled time period during which a DOH authorized syringe exchange program exchanges syringes with clients in accordance with these regulations.

[9/30/99; Recompiled 10/31/01]

# 7.4.6.8 GENERAL PROVISIONS GOVERNING SYRINGE EXCHANGE PROGRAMS:

- A. Community health services providers with relevant experience in providing disease prevention services, health care services, social services or substance use treatment services to injection drug users are eligible to apply to provide syringe exchange programs to the department of health in accordance with the Harm Reduction Act and these regulations.
- B. Community health services providers that seek to implement authorized syringe exchange programs must submit a written proposal to the infectious diseases bureau of the New Mexico department of health that includes a syringe exchange program as part of a comprehensive harm reduction program to reduce the transmission of infectious diseases among injection drug users and encourage intravenous drug users to seek substance abuse treatment. The proposal must include:

- (1) estimates of the number of injection drug users to be served and the information on which the estimate is made;
- (2) definition of the geographic area to be served by the syringe exchange and harm reduction program;
  - (3) the proposed schedule and sites for syringe exchange sessions;
- (4) a list of the proposed harm reduction program staff and volunteers, and a description of their credentials including education and experience, qualifications and skills that relate to participation in a harm reduction program;
- (5) a description of the community health service provider's experience in providing relevant services to injection drug users;
- (6) a description of the harm reduction program services proposed to be provided directly by the community health;
- (7) a description of harm reduction program services proposed to be provided to syringe exchange program clients through referral to other agencies and a description of the referral mechanisms that are proposed to be used;
- (8) a description of efforts proposed by the community health service provider to solicit participation by residents, business owners, law enforcement officials and injection drug users in the design and implementation of the proposed syringe exchange program;
- (9) a description of security precautions for ensuring the confidentiality of syringe exchange and harm reduction program records;
- (10) a description of injection control practices and needle stick accident protocols; and,
- (11) a statement confirming that if approved, the community health service provider will participate in department of health authorized syringe exchange program evaluation activities as required.
- C. The department of health shall review the proposals to determine whether they meet the statutory and regulatory requirements and whether there are sufficient numbers of unserved injecting drug users to justify the proposed Harm Reduction Act activities. Upon approval of the harm reduction program proposal, the community health service provider will be issued an agreement under which it is authorized to conduct a harm reduction program (including a syringe exchange program) under the auspices of the Harm Reduction Act for a period of one year. This authorization does not supersede other contractual arrangements between the department of health and the community health service provider.

- D. Community health service providers that implement harm reduction programs must not utilize personnel, equipment or other resources funded by federal programs for the syringe exchange program. These resources may be used, however, for other harm reduction program activities that are demonstrably separate from the syringe exchange program.
- E. Department of health authorized syringe exchange programs, must comply with regulations issued by the department of health. Failure to do so is grounds for revocation of the department's authorization to perform Harm Reduction Act activities including the syringe exchange program. Authorization to perform Harm Reduction Act activities is also subject to the availability of funds as determined by the department of health.
- F. Department of health authorized syringe exchange and harm reduction programs must cooperate with the department of health in efforts to evaluate the efficacy of syringe exchange and harm reduction programs.
- G. Department of health authorized syringe exchange programs must demonstrate that they respond to and make reasonable efforts to resolve all reasonable concerns raised by citizens of the neighborhoods in which the Harm Reduction Act activities are performed as well as reasonable concerns raised by community groups, community business people, law enforcement agencies and the department of health.
- H. Department of health authorized syringe exchange programs are required to coordinate their efforts with other syringe exchange programs throughout the state to avoid duplication of efforts.
- I. Department of health authorized syringe exchange programs must identify one qualified individual within their organization to serve as the syringe exchange and harm reduction program supervisor who is responsible for the performance of all Harm Reduction Act activities.

[9/30/99; Recompiled 10/31/01]

#### 7.4.6.9 CLIENT ELIGIBILITY AND ENROLLMENT:

- A. Only current injection drug users are eligible to be enrolled in the department of health authorized syringe exchange program.
- B. The New Mexico Harm Reduction Act requires that participating clients carry a department of health issued card while participating in syringe exchange program activities that identifies the person as a participant in a department of health authorized syringe exchange program that is conducted in accordance with the Harm Reduction Act standards.
- (1) The membership card shall not bear the client's name, but it must have unique identifying information for that specific client. The membership number will be a code

generated from letters of the first and last name and from the client's birth date. The client can use the card to demonstrate that the client is an enrolled syringe exchange program participant who is in possession of hypodermic syringes or needles at the time he is directly and immediately engaged in a harm reduction program as provided in the Harm Reduction Act.

- (2) Upon enrollment, a department of health authorized Harm Reduction Act program, each new client will be required to accurately complete an intake form about his/her current drug use, needle sharing habits, syringe disposal habits and the client's thoughts about their recovery options. All information provided to the syringe exchange program by people seeking enrollment is confidential pursuant to state and federal law, except for the information the department of health requires the syringe exchange program to provide.
- C. Enrollment of clients in a department of health approved syringe exchange program.

#### (1) Eligibility:

- (a) Eligibility is limited to citizens of the state of New Mexico who are 18 years of age or older.
- (b) People seeking enrollment into syringe exchange programs are required to be current injection drug users.

# (2) Enrollment:

- (a) People seeking syringe exchange program enrollment must present personal identification that confirms the information used to generate the syringe exchange program identification number (the required information includes, first name, last name, and date of birth).
- (b) Syringe exchange program clients are allowed to exchange syringes at any department of health authorized syringe exchange program in the state of New Mexico. However, clients must seek initial enrollment in only one program. Syringe exchange program clients shall not be enrolled in more than one active authorized program at a time.
- (c) People seeking department of health authorized syringe exchange program enrollment must participate in completing a program intake survey. This requirement cannot be waived except by the medical director of the infectious disease bureau in the event of compelling, documented extenuating circumstances.
- (d) All information provided to the syringe exchange program by people seeking enrollment is confidential pursuant to New Mexico law (Section 24-1-20 NMSA 1978) and federal law, except for the information that the department of health requires the syringe exchange program to provide for the purposes of program regulation and evaluation.

- (e) Once eligibility has been confirmed and the intake form has been completed as required, the department of health authorized syringe exchange program clients will be issued a department of health authorized syringe exchange program participant card. The syringe exchange program staff will enter the syringe exchange program identification number and the membership expiration date (one calendar year following the date of enrollment) on the membership card. The card will then be laminated and given to the client.
- (f) Department of health authorized syringe exchange program clients must be instructed by syringe exchange program staff at the time of enrollment that the syringe exchange program membership card is for the use of the person to whom the card was issued only. Clients are required to carry the membership card when they are transporting syringes to and from the department of health authorized syringe exchange sites. Clients must be informed that syringe exchange program participation will not prohibit their arrest or prosecution for the possession of syringes at times other than when they are directly and immediately engaged in a Harm Reduction Act activity, pursuant to the Controlled Substance Act (Section 24-2C-1 et seq. NMSA 1978).
- (g) Department of health authorized syringe exchange program clients should be provided with 30 program syringes at the time of enrollment. The authorized syringe exchange program must inform the clients that all subsequent exchanges will involve exchanging one used syringe for one sterile program syringe. The syringe exchange program must inform the client that each client who is enrolled in a department of health authorized program can exchange a maximum of 200 syringes per syringe exchange session.
- (h) Department of health authorized syringe exchange program clients must be given a schedule of the program's syringe exchange sessions, harm reduction program education information, a harm reduction kit and information about drug treatment options.
- (i) Department of health authorized syringe exchange program clients must be instructed at the time of enrollment that they should clean their syringes with bleach and water before bringing them to syringe exchange sites.
- (j) Department of health authorized syringe exchange program clients must be informed that failure to comply with syringe program rules can result in disenrollment and revocation of their department of health authorized syringe exchange program participation card.
- (k) The syringe exchange program must keep all enrollment records in a secure location with appropriate safeguards against theft or tampering. Any misappropriation, falsification or theft of department of health authorized syringe exchange program membership cards must be reported immediately to the infectious diseases bureau of the department of health. Failure to do so will result in the revocation of the department of health approval to operate a syringe exchange program.
- (l) All department of health authorized syringe exchange programs must provide the department of health with original client intake surveys and enrollment information for each calendar month not later than the fifteenth day of the following month.

# 7.4.6.10 SYRINGE EXCHANGE PROGRAM REQUIREMENTS:

- A. The syringe exchange program must maintain a regular and predictable schedule for syringe exchange sessions that promotes participation by clients, staff and volunteers. The program should seek the advice of clients in determining the schedule of syringe exchange sessions and locations. The syringe exchange session schedule must be approved by the department of health, prior to its implementation, and the syringe exchange program must notify the department of health of any modifications to the schedule as soon as possible. The new schedule shall not be implemented before department of health approval has been received.
- B. The syringe exchange program must provide information to syringe exchange program clients about the scheduled hours, dates and locations for syringe exchange sessions.
- C. The syringe exchange program must demonstrate that it has attempted to address and resolve all neighborhood concerns regarding hours, dates and locations for syringe exchange sessions. The syringe exchange program shall conduct syringe exchange sessions in a manner that does not promote loitering, unruly behavior, unlawful activities, or that in any way detracts from the safety and serenity of the neighborhood. The syringe exchange program must notify the department of health within 72 hours of any concerns or complaints received by the program, its staff or volunteers.
- D. The syringe exchange program must have at least two syringe exchange program staff present at all times at the exchange site during syringe exchange sessions. Staff members must be 18 years of age or older and must not be active users of illicit drugs. Syringe exchange program staff must be approved for participation in the syringe exchange program by the department of health. Staff members must carry syringe exchange program cards that identify them as department of health authorized syringe exchange program staff.
- E. All syringe exchange program staff must be vaccinated against hepatitis B virus if they are not immune to hepatitis B virus unless they have a specific contraindication for receiving the hepatitis B vaccine. People who have been vaccinated against hepatitis B virus or infected with hepatitis B in the past may be immune. An HIV early intervention nurse or other public health staff of the department of health can administer a simple blood test to determine immunity to hepatitis B. The department of health will administer hepatitis B vaccine to syringe exchange program staff at no cost. Repeat vaccinations are required one month later and then six months later. All three shots are required for the vaccine to be effective at preventing hepatitis B virus infection.
- F. Syringe exchange program staff must teach all syringe exchange program clients to wash their used syringes out with water and bleach before they bring them in to be exchanged. This cleansing procedure helps to reduce the chance that used syringes are contaminated with hepatitis B, hepatitis C or HIV. Clients must be told to bring used needles in with the caps on the

needles if possible. Except under unusual circumstances, the clients should handle their used syringes themselves during the exchange and deposit them directly into the biohazardous waste (sharps) container. It should not be necessary for the syringe exchange program staff to handle the used syringes and syringe exchange program volunteers should never handle used syringes.

- G. Syringe exchange program staff must always wear medical gloves when handling used syringes or when handling biohazardous waste (sharps) containers. A sharps container approved by the U.S. occupational safety and health administration must be used. The outside of the sharps container must be cleaned with disinfectant and bleach at the beginning and end of each syringe exchange session.
- H. Syringe exchange program staff must never directly touch a used syringe, even with gloved hands. syringe exchange program staff must use tongs to handle the used syringes and keep the syringe far away from the staff person's body or anyone else's body. Syringe exchange program staff must never try to re-cap a syringe, or hold a used syringe over any part of the handler's body.
- I. The syringe exchange staff must ask the syringe exchange program client to drop the used syringes into a sharps container one at a time as soon as possible during the exchange. Used syringes shall not be placed or allowed to accumulate outside of the biohazardous waste container.
- J. The syringe exchange staff must never reach into a sharps container, force syringes down into the mouth of a sharps container or overfill a sharps container.
- K. The syringe exchange staff must always put the cover on the mouth of the sharps container when the sharps container is not being used or when it is full.
- L. In addition to the two syringe exchange program staff members, the syringe exchange program may include syringe exchange program volunteers in the staffing of a syringe exchange session. Volunteers must be at least 18 years of age and must not be injecting or illicit drug users, unless they are enrolled and participating in all facets of the Harm Reduction Act activities. Volunteers must carry program cards that identify them as syringe exchange program volunteers.
- M. The syringe exchange program must maintain at the syringe exchange session site a copy of the department of health letter authorizing the program to conduct a syringe exchange program, a copy of the Harm Reduction Act, a copy of the syringe exchange program policies and list of emergency telephone numbers.
- N. The syringe exchange program must make a telephone (fixed or mobile) available to syringe exchange program staff during the syringe exchange session.
- O. Syringe exchange program staff and volunteers must treat syringe exchange program clients respectfully and in a manner that promotes client enrollment, participation and retention.

- P. Syringe exchange program staff must have the prerogative to shut down a syringe exchange session in the event of any occurrence that affects the safety, security, confidentiality or effectiveness of a session.
- Q. Syringe exchange program staff must shut down a syringe exchange session in the event of any violent act or threat of violence. Staff must have the option to summon the police in the event of an occurrence that raises security concerns.
- R. Syringe exchange program staff and volunteers must comply with legitimate requests from law enforcement officers and staff must not interfere in any way with a law enforcement officers in the performance of their lawful duties.
- S. Syringe exchange program staff must immediately report to the department of health all needle stick accidents, violent acts, incidents involving law enforcement agents, and arrests of syringe exchange program clients, staff or volunteers during a syringe exchange session.
- T. Syringe exchange programs should provide 30 program syringes to newly enrolled syringe exchange program clients. Newly enrolled clients are not required to bring in used syringes for exchange. Subsequently, the program should provide one sterile program syringe for each used syringe brought in by the client for exchange. The total number of sterile program syringes issued a participant during a syringe exchange session must not exceed the total number of used syringes brought in by the participant for exchange and the maximum number of syringes given any participant must not exceed 200 in any syringe exchange session.
- U. Syringe exchange programs should provide equipment for cleaning used syringes, such as bleach kits, to syringe exchange program clients.
- V. Syringe exchange programs should provide risk-reduction materials to syringe program clients to increase the safety of sexual activity.
- W. Syringe exchange program staff must maintain logs of syringe exchange session events that include:
- (1) the syringe exchange program participant card numbers of syringe exchange program clients who exchanged syringes;
  - (2) the number of used syringes that were brought in by each client for exchange;
  - (3) the number of program syringes that were issued to each client;
  - (4) the harm reduction program activities that were offered to each client;
- (5) the harm reduction program activities in which each client elected to participate;

- (6) written reports of any client complaints about the syringe exchange program;
- (7) written reports of any complaints about the syringe exchange program made by members of the community; and,
- (8) written reports of any interactions between law enforcement agents and participants in the syringe exchange session.
- X. Syringe exchange programs will provide copies of the complete syringe exchange logs for each calendar month to the infectious diseases bureau of the department of health not later than the fifteenth day of the following month.
- Y. Syringe exchange programs will assure the safe and legal disposal of biohazardous waste containers that contain used syringes collected during syringe exchange sessions.
- Z. By prior arrangement, syringe exchange programs must accommodate requests from the department of health to conduct public health interventions or syringe exchange program evaluations at syringe exchange sessions.
- AA. If a person is stuck with a contaminated needle, it is very important to seek medical attention immediately. The department of health recommends beginning HIV medications within 1 or 2 hours of a needle stick accident whenever possible. In the event the skin is broken by a contaminated needle, the needle-stick accident protocol contained in the syringe exchange program protocol book should be followed and the person who has been stuck should go to the nearest emergency room as quickly as possible for treatment.
- BB. Syringe exchange program staff who have had a needle stick accident, should have their blood tested again two months and six months after the needle stick to make sure that they have not been infected with hepatitis B, hepatitis C or HIV.

[9/30/99; Recompiled 10/31/01]

# 7.4.6.11 SYRINGE EXCHANGE PROGRAM CLIENT REQUIREMENTS:

- A. Syringe exchange program clients must present their syringe exchange program participant card to syringe exchange program personnel in order to exchange syringes. Program staff should challenge the validity of the participant card if it is questionable and clients should be prepared to provide information that will confirm their membership to program staff.
- B. Syringe exchange program clients may request that the syringe exchange program provide one sterile program syringe for each used syringe that the client brings to the syringe exchange session. Clients may exchange up to, but not more than, 200 syringes per syringe exchange session.

- C. Syringe exchange program clients should clean used syringes intended for exchange with water and bleach before coming to the syringe exchange session in order to reduce the risk of infectious disease transmission. Clients should bring used syringes to the syringe exchange session with the needles capped.
- D. During the syringe exchange session, the syringe exchange program client should carefully drop each used syringe into the biohazardous waste container one at a time while a syringe exchange program staff member counts the number of used syringes. These numbers must be recorded in the syringe exchange session log.
- E. Syringe exchange program clients should treat syringe exchange program staff and volunteers courteously.
- F. While in the vicinity of the syringe exchange site, syringe exchange program participants must conduct themselves in a manner that does not attract negative attention to the syringe exchange program. Participants must not loiter at the syringe exchange site after they have concluded their syringe exchange activities.
- G. Syringe exchange program clients must not carry weapons or illicit drugs to the syringe exchange session.
- H. Syringe exchange program clients must abide by the rules and regulations of the syringe exchange program. Failure to do so could result in disenrollment from the program.

[9/30/99; Recompiled 10/31/01]

**HISTORY OF 7.4.6 NMAC:** [RESERVED]

# New Mexico Department of Health (NMDOH) Public Health Division (PHD) Protocol

# Harm Reduction Protocols November 2011 Revised January 2012

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#### **INTRODUCTION**

This protocol updates and consolidates the guidance for operations of several Public Health Division efforts. Although somewhat controversial, these efforts have demonstrated effectiveness in reducing the risk of injury, infectious disease transmission, and death in communities from injection drug use and overdose. Continued operations of these efforts is dependent on limited and vulnerable resources – efficient and appropriate use of the available resources is critical for the continued operations of these efforts.

This protocol addresses two services: 1) Syringe Exchange, and 2) Overdose Prevention Training/Naloxone.

# 1) SYRINGE EXCHANGE SERVICES

# **Background**

Syringe exchange provides significant cost savings to the State by preventing the spread of infectious diseases. Research has shown that syringe exchange programs (SEP) have positively impacted communities in many ways, including a reduction in the number of improperly discarded needles on streets and in parks, a reduction in costly emergency room visits by individuals suffering from injection related complications (e.g., abscesses), and other quality of life indicators. SEP's are often the first "point of contact" for many IDU's, who may become re-integrated into their communities by participating in services such as testing, immunizations, family planning and prenatal care, and referrals for various social services and available substance abuse treatment services.

This clinical protocol provides direction for the provision of syringe exchange and related interventions to adult injection drug users as mandated by the New Mexico State Legislature in the 1997 HARM REDUCTION ACT (24-2C-1 to 24-2C-6 NMSA 1978). The objective is to eliminate the re-use and sharing of syringes and other injection equipment by injection drug users (IDU) in order to prevent the transmission of the human immunodeficiency virus (HIV), hepatitis B and C viruses (hepatitis B and C), and other bloodborne diseases. A secondary objective is to reduce the uncontrolled disposal of potentially contaminated sharps, thereby reducing the risk of injury and bloodborne pathogen transmission in community settings. Participants in the program can also access immunizations, individual counseling and education to decrease the risk of transmission of bloodborne diseases and other injection related complications (e.g., abscesses), and assistance in accessing substance abuse treatment services.

Under the Harm Reduction Act (specifically, NMSA 24-2C-4) the New Mexico Department of Health (NMDOH) is charged with establishing and administering a harm reduction program for the purpose of sterile hypodermic syringe and needle exchange, and compiling data to assist in planning and evaluating efforts to combat the spread of bloodborne diseases. NMSA 24-2C-5 states that the harm reduction program shall provide sterile hypodermic syringes and needles in exchange for used hypodermic syringes, needles, or other objects used to inject controlled substances or controlled substance analogs into the human body; provide education to participants on the transmission of HIV, hepatitis B, and hepatitis C; and provide referral to substance abuse treatment services for participants.

This protocol will increase syringe access in New Mexico by supporting Regional Health Office staff and other providers in implementing and incorporating syringe exchange for injection drug users into the spectrum of prevention health services offered by the NMDOH. Due to the high prevalence of substance abuse and related factors (such as hepatitis C and drug overdose), a low rate of HIV, and the largely rural nature of New Mexico, the Regional Public Health Offices play a key role in communities not served by community-based organizations offering more comprehensive disease prevention and outreach services.

# **Service Population**

The populations that fall under the harm reduction/SEP protocol are active or former users of illicit intravenous drugs, 18 years of age and older. In some cases, uninsured or indigent people with diabetes may qualify for services.

Clinical populations that may receive services under this protocol include, but are not limited to, those served by:

- NMDOH Public Health Offices
- NMDOH Sexually Transmitted Disease Clinics
- NMDOH HIV/AIDS Prevention and/or community-based HIV/hepatitis Counseling and Testing agencies
- NMDOH and/or community based Substance Abuse Treatment providers
- Social Service agencies
- Diabetes Prevention and Control providers
- Diabetes Educators

# Methodology

Syringe exchange must be included as a component of public and community health services. Providers should have some relevant experience in providing disease prevention services, health care, social services, or substance use treatment services to IDU's. Training is available if they do not have experience.

# 1. Implementation and General Provisions

# Personnel

A program or office planning to provide syringe exchange/harm reduction services must identify one qualified individual within their organization to serve as the Harm Reduction Program Coordinator who is responsible for the performance of all harm reduction activities.

The program or office must identify all proposed harm reduction program staff and volunteers. SEP staff and volunteers may not be active users of illicit drugs. It is recommended that former users of illicit drugs have not used drugs for at least two years before providing syringe exchange services to active users.

A minimum of two staff, including the Coordinator, is recommended. Proposed staff should possess some education and/or work experience, qualifications, and skills in providing services to IDUs. In addition, participating staff must also be trained and certified by the Infectious Disease Bureau Harm Reduction Program in order to provide syringe exchange services. This certification must be renewed every two years.

The program or office must inform any other program entities with which they share a facility or location of the implementation of syringe exchange. Reasonable efforts should be made to prevent and/or to overcome concerns or objections raised by other staff or programs, or local governments. As a legislative mandate for NMDOH to provide syringe exchange to IDUs in New Mexico exists, explicit permission need not be requested or granted by other programs or local governments. Assistance in implementing a SEP in any Public Health office will be provided by the Regional

Disease Prevention Team, the Harm Reduction Program Manager, and the Infectious Disease Bureau.

The program or office should engage residents, business owners, law enforcement officials, criminal justice officials, local health councils, and IDU's in the design and implementation of any proposed SEP. Any efforts to engage and/or educate the larger community must be planned and coordinated with, and use the resources of, the Harm Reduction Program. Periodic re-education may also be necessary due to administrative or staff changes.

The program or office must demonstrate that they will respond to and make reasonable efforts to resolve all practical concerns raised by citizens of the neighborhoods in which the harm reduction activities are performed, community groups, community business owners, law enforcement agencies, program participants, and the NMDOH. A local SEP must notify the Harm Reduction Program in writing within 72 hours of any concerns or complaints received by the program, its staff or volunteers. The Harm Reduction Program and Infectious Disease Bureau may provide resources and assist in the resolution of such complaints.

#### Site

The program or office must identify a proposed schedule and site, room, or area for syringe exchange sessions.

The program or office must provide a description of security precautions for ensuring the confidentiality of syringe exchange and harm reduction program records. This includes maintaining client confidentiality with regards to harm reduction program participation when transitioning a participant to other "in-house" services, such as family planning, WIC, and testing/immunizations.

#### Documentation

Syringe exchange activities do not require the use of a medical record, although participants should be notified when being transitioned into other services that a medical chart, including their name, may be generated. It is the responsibility of the participant to decide whether or not to divulge SEP participation and issues related to injection or other drug use to staff providing other services. This information should not be explicitly included in a referral originating from a syringe exchange provider.

#### Other Issues

The program or office must provide SEP participants with referrals to other services and agencies, both local and state.

The program or office must abide by accepted NMDOH infection control practices and needle-stick injury protocols. Proper bio-waste storage and disposal must also be available for the storage and removal of the collected used syringes and injection equipment. Procedures for the management of needle-stick injuries should be available and readily accessible to staff.

The program or office must comply with all regulations, policies, and procedures issued by the NMDOH. Failure to do so is grounds for revocation of the department's Page 5 of 29

authorization to perform harm reduction activities including the SEP. Authorization to perform harm reduction activities is also subject to the availability of funds as determined by the NMDOH.

Syringes, sharps disposal containers, and related injection and safety equipment is provided by the Harm Reduction Program and distributed to participating programs or offices through an identified warehouse serving each Public Health Region.

#### 2. Program Operation

The SEP must maintain a regular and predictable schedule for syringe exchange sessions that promotes participation by program participants, staff, and volunteers. The program should seek the advice of participants in determining the locations and schedule of syringe exchange sessions. It is suggested that any necessary schedule modifications occur at least six or more months ahead of time. The SEP must notify the Harm Reduction Program of any modifications to the schedule.

The SEP must provide information to participants about the scheduled hours, dates, and locations for syringe exchange sessions. If a holiday falls on a regularly scheduled session, sufficient notice should be provided to program participants. If possible, an alternate date may be provided.

There must be at least two program or office personnel on premises at all times at the exchange site during syringe exchange sessions. In addition, there must be a telephone available to program staff or volunteers during syringe exchange sessions. SEP staff and volunteers may not, under any circumstances, trade, exchange or otherwise provide money or drugs, or engage in sexual relations, with program participants. Buying or selling items of any nature during a syringe exchange session, or at the program or outreach location, is prohibited - violation of this rule by an individual will result in the revocation of provider certification for a minimum of one year, as well as additional disciplinary action. Failure by a program to enforce this rule will result in the revocation of NMDOH authorization to perform syringe exchange activities through the end of the funding cycle.

The largely rural nature of New Mexico increases the likelihood that a provider may be related or otherwise personally involved with a program participant outside of the work environment. It is appropriate, although not always possible, for an individual in this situation to request that another staff member or volunteer provide the syringe exchange or related service to the participant. When it is not possible, the staff member must take care to not engage in any of the aforementioned activities with the participant during the syringe exchange session, or at any other time at the program or office location. Violation of this rule will result in disciplinary action.

SEP staff and volunteers must treat SEP participants respectfully and in a manner that promotes participant enrollment, participation and retention. Inappropriate behavior by staff that is reported by a participant will be investigated by the program's supervisor or Regional leadership and the NMDOH Infectious Disease Bureau, and may result in disciplinary action.

Conversely, participants are required to observe the same standards of behavior expected of other clients and consumers of available services. Failure to do so should be addressed with disciplinary action consistent with existing program or office policy and may include exercising the right to refuse service to an uncooperative or hostile participant.

The right of a provider to refuse service for an extended length of time to a "problem" participant should be carefully considered, and it is recommended that such a decision be made jointly by all program or office staff. Substance use/abuse often co-occurs with other mental or emotional conditions, and participants who present as unwilling or unable to comply or function within a program or office, or socially acceptable norms, are often the most "at risk" individuals. Suggestions for working with a consistently difficult participant include:

- Calmly asking an agitated or hostile participant to step outside and return when they have calmed down
- Asking the participant if they would be willing to meet privately with program staff
  to discuss the situation and participate in resolving issues, such as developing a
  "behavior contract" or similar effort to engage an individual's sense of self and
  mutual respect
- Refusing service for a limited time, such as a few days or few weeks, may be appropriate. In this event, provide the participant with information about alternative sources where they might be able to access syringe exchange services
- Regardless of the imposed length of time the participant has been asked not to return, program or office staff should remain flexible, and are encouraged to meet with the participant if they are ready to cooperate

Selling, buying, and using drugs on or near a SEP, office, or outreach location or vehicle is not allowed. A participant involved in these activities should be respectfully confronted immediately and the activity stopped. Refusal of service for up to one year may be appropriate for a participant who repeatedly disregards this rule.

#### 3. Staff Safety

Violent acts, or any threat of violence by a program participant towards other participants or program staff and volunteers will not be tolerated. Participants are not allowed to carry weapons on or near the program or office property, or outreach vehicle or location. Weapons may include, but are not limited to, large or sharp sticks, knives, guns, or any device or object presented in a threatening manner. Should a participant be seen to carry a weapon, they should be respectfully asked to leave immediately and not return with the weapon. If it is discovered and confirmed that a participant has used services while carrying a concealed firearm during a syringe exchange session, it is appropriate to refuse services to that participant for a minimum of one year.

A hostile or agitated participant bearing a weapon should not be directly confronted. The site should be shut down immediately, with all other clients and staff made to exit or leave the premises or site. The participant should be notified that law enforcement will be summoned if they do not leave, and that they are expelled from the particular

program for a minimum of one year following the incident, and may be permanent. It is recommended that one or more staff receive training on conflict resolution and deescalation techniques.

SEP staff have the prerogative to cancel a syringe exchange session in the event of any occurrence that affects the safety, security, confidentiality, or effectiveness of a session. Program staff must shut down a syringe exchange session in the event of any violent act or threat of violence. Staff have the option to summon the police in the event of an occurrence that raises security concerns.

Involving, or the threat of involving, the police should only be used as a last resort, or for responding to an emergency. Use, or over-use, of this response towards participants directly compromises the element of trust necessary for the success of any SEP. "Word of mouth" travels through the IDU community quickly and may not only diminish participation, but may put outreach personnel in danger of retaliation while out in the field, or in staff members' personal lives.

Program staff and volunteers must not interfere or obstruct law enforcement personnel who may be involved in a situation with a program participant while performing their duties. SEP staff must immediately report to the NMDOH all violent acts, incidents involving law enforcement agents, and arrests of SEP participants, staff, or volunteers during a syringe exchange session.

# **Standard Precautions**

In compliance with Occupational Safety and Health Administration regulations, the NMDOH requires that all clinical staff who provide direct client care in the course of their work complete annual bloodborne pathogen training. To this end, the PHD Health and Safety Committee program maintains an online Bloodborne Pathogen Course available through the NMDOH Online Learning Center (http://training). This course is intended to be used in conjunction with supervisor or classroom bloodborne pathogen "face-to-face" training. Upon successful completion of the course, staff should print a copy of their BBP Course Certificate and provide it to their supervisor.

All SEP staff must be vaccinated against the hepatitis B virus if they are not immune to the hepatitis B virus, unless they have a specific contraindication for receiving the hepatitis B vaccine. The NMDOH will administer the hepatitis B vaccine to SEP staff at no cost.

#### **Sharps Management**

Participants must transport used syringes in a recommended or approved sharps container. Any puncture resistant container as recommended by the Environmental Protection Agency is sufficient. Current EPA guidelines include using a thick plastic shampoo or laundry detergent bottle with a secure lid. However, participants are strongly encouraged to use sharps containers for their used syringes: the Harm Reduction Program makes a variety of sizes available for program participants to choose from. Glass bottles, aluminum cans, plastic soda bottles, or metal coffee cans are strongly discouraged. Syringes in non-puncture proof containers, such as cardboard boxes or bags, jeopardizes the immunity granted to program participants should they encounter a law enforcement official while transporting used syringes.

The syringe exchange staff must ask the SEP participant to drop the used syringes into a sharps container. SEP staff must never directly touch a used syringe, even with gloved hands: SEP staff must use tongs to handle used syringes. Participants should not be made to empty used syringes from a container for the purpose of verifying the requested exchange amount. If the provider is not convinced of the reported amount, it is reasonable to bargain with the participant for an acceptable exchange.

The SEP is considered the "waste generator". By law, the waste generator must assure, and is responsible for, the safety of regulated medical waste from the time it is collected until it is destroyed or otherwise neutralized (a 'certificate of destruction' is provided by the program to document this). This assurance includes the time that syringes are in the possession of the waste management transportation service.

- NOTE: All contaminated sharps must be in an approved sharps container before being placed in a red bio-hazard disposal bag, even if that bag is in a larger bio waste storage container. Any non-approved container, such as a shampoo or laundry detergent bottle, must also be placed inside of an approved container before being "red bagged." The red bag must be tied with a single slip knot before transport. Failure to comply with these procedures places waste transportation and disposal personnel at risk for injury and is a violation of state and federal environmental law, and may result in fines.
- If using a "PG II" container (approved by DOT for transport), items and nonapproved containers may be placed directly into that container and no red bag is required. These containers will have locking lids with a leak proof gasket. These containers are made available to providers by the Harm Reduction Program.

SEP staff must immediately report to the NMDOH all needle-stick injuries involving SEP participants, staff, or volunteers during a syringe exchange session. The NMDOH recommends, and will provide, post exposure prophylaxis for possible HIV infection in the event of a needle-stick exposure by a program provider.

#### 4. Required Documentation

Required documents for program operation include:

- First Interview forms
- Re-interview forms
- SEP Daily Exchange Log Form (Log Forms)

SEPs will provide copies of these forms for each calendar month to the Infectious Disease Bureau of the NMDOH no later than the tenth day of the following month. It is recommended that a program or office maintain the original documents on file for at least five years. These documents should be kept in accordance with security precautions for ensuring the confidentiality of syringe exchange and harm reduction program participants and records.

A SEP shall keep a log of the ID codes of all participants enrolled by that program. In the event that a participant needs a replacement ID card before the one year expiration

date, the program can provide it without having to re-interview the participant while maintaining the correct expiration date.

SEP staff shall maintain logs of syringe exchange session events that include:

- the card number of SEP clients who exchanged syringes;
- whether the recorded visit was a new enrollee, or the participant was re-enrolled into the program based upon the annual expiration;
- the number of used syringes that were brought in by each participant for exchange;
- the number of program syringes that were issued to each participant;
- the number of people, including the participant, who will receive needles from the exchange ("secondary exchange");
- whether HIV/hepatitis screening, results, or vaccines have been provided (do not record the actual test result);
- referrals provided to the participant;
- written reports of any participant complaints about the SEP;
- written reports of any complaints about the SEP made by members of the community;
- written reports of any interactions between law enforcement agents and participants in the syringe exchange session; and,
- if syringes are provided to a previously enrolled participant who did not bring any to exchange, the reason for the provision should be written in the "comments" box.

#### 5. Other Service Provisions

SEPs should provide, or have available, risk-reduction materials and condoms for syringe program participants to increase the safety of sexual activity. Staff should be available to answer questions concerning sex and the risks associated with sex and substance use/abuse.

SEPs should provide, or have available, educational resources for program participants about safer injection practices, vein care, and related health issues to assist participants in reducing injection related complications. This includes abscess care and reducing the long term health consequences of the drugs themselves. Program staff should be aware of local healthcare resources (e.g., Federally-Qualified Health Care facilities, local health office, urgent care, etc.) in case the participant needs to be referred for services (e.g., cellulitis/abscess management, STI testing).

SEP's should provide injection related equipment made available by the Harm Reduction Program including: two sizes of syringes (28g 1/2 cc or 1 cc insulin syringes), personal SHARPS containers and other 'works' as they are available through the Harm Reduction Program.

It is suggested, though not required, that programs have items such as bottled water, snacks, and personal hygiene supplies for participants.

# 6. Client Eligibility

The criteria for enrollment into the Harm Reduction Program are:

- A. Individual must be 18 years of age or older.
  - 1. It is up to the provider to determine if an individual meets the minimum age requirement.
  - 2. The provider may require a driver's license or state ID to verify an individual's age. If that individual is not able to confirm their age, the provider may refuse enrollment at that time. A driver's license or other form of ID is not required if an individual's age is not in question.
  - 3. The Controlled Substances Act (30-31-1 NMSA 1978) states that a person eighteen years of age or over who violates the provisions of Subsection B of Section 30-31-25.1 NMSA 1978 by delivering drug paraphernalia to a person under eighteen years of age and who is at least three years his junior is guilty of a fourth degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978.
- B. Individual must use, or have used, syringes for injection drug administration.
  - 1. A person seeking enrollment must be a current injection drug user.
    - "Current injection drug user" is generally defined as someone who
      has self-administered a controlled substance by injection at least
      once in the 30 days prior to seeking enrollment with a syringe
      exchange provider.
    - As an example, at, or near the beginning of the enrollment process, the syringe exchange provider may casually ask the person seeking enrollment: "Where do you fix (inject)?" The individual should be able to answer the question without hesitation and/or show the provider "tracks" (marks such as scars or scabs clustered together on the skin where veins are closest to the surface, like the inside of the arms, hands, ankles, and even the neck).

OR,

- 2. An individual who injected in the past (former user), but who has not engaged in that activity for an extended period of time (longer than 30 days prior to seeking enrollment) either by choice, such as participating in substance abuse treatment, or by force, such as jail or prison, is eligible for enrollment with the SEP.
  - Former users seeking enrollment should be able to display "tracks," or be able to accurately and lucidly discuss drug use and injection practices.
  - The syringe exchange provider should attempt to respectfully engage a former user seeking enrollment in a discussion about possible alternatives to re-initiating injection practices.

OR.

 (In select case) a person who requires the use of syringes for legitimate medication administrations (e.g., insulin for diabetes, Coumadin/warfarin, etc.).

- The clients should have a compelling financial reason for participation in the program. However, a verification of financial eligibility is not required for participation.
- C. Individual should be a resident of New Mexico.
  - 1. A non-resident of New Mexico may enroll and receive services in the program; however,
  - 2. The Harm Reduction Act is a New Mexico State law, and as such, only provides an exemption to the state's paraphernalia statute to residents of New Mexico who are enrolled in the SEP.

The syringe exchange provider must inform both resident and non-resident participants that enrollment in the program does not afford them any protection for possessing paraphernalia once outside of the State of New Mexico, or on Federal or Tribal lands.

#### 7. Enrollment

Individuals seeking NMDOH authorized SEP enrollment must complete a program intake survey using the "SEP Interview" form.

- A. SEP staff must administer the intake survey rather than have the client fill it out. All information provided to the SEP by individuals seeking enrollment is confidential pursuant to New Mexico law (Section 24-1-20 NMSA 1978) and federal law.
  - 1. The survey is designed in part to collect demographic, risk behavior, drug use, knowledge of disease status, and other data.
  - 2. It also serves as a motivational interviewing tool to help facilitate discussion and provide counseling opportunities.
  - 3. The top of the survey has a key to help generate the participant code that will go on the yellow "sharps" program ID card. This code is used primarily for data tracking, but can be used to identify the individual as a Harm Reduction Program participant should the individual have an encounter with law enforcement where possession of paraphernalia may be in question (see B., below).
- B. After the enrollment survey is completed and the exchange has been logged, participants must receive the yellow SHARPS Card with their personalized ID code. It is highly recommended, though not always possible, to laminate the card before giving it to the participant. The card should contain an expiration date one year, to the month, from the time the participant is enrolled.
  - The syringe exchange provider should inform all participants that the SHARPS Card can positively identify the individual as a member of the program, but it will not serve as, nor be accepted as, an ID card by law enforcement or in any other context.
  - 2. Participants must always have a SHARPS Card when they leave an exchange site with syringes and/or supplies. Both the participant and the provider may be liable for possession/distribution of paraphernalia if a participant is stopped by police after leaving the site if they cannot demonstrate their participation in the program.
  - 3. Participants should be made aware of the description of the law, and of the NMDOH phone number on the back of the card. They may direct law

- enforcement or others seeking information on participant enrollment status to call this number.
- 4. The syringe exchange provider should inform all participants that enrollment in the program does not supersede other legal conditions, rules, or restrictions such as probation and parole.
- 5. Participants must be instructed to identify themselves to law enforcement personnel as program participants in the event they have an encounter that results in a search of either themselves or their property. They should then disclose the location of the syringes so an officer is not injured. This often results in a more positive interaction between the participant and the officer(s).
- 6. Participants should be warned that program participation does not protect against testing of used syringes for residue therefore, participants should be warned to rinse all syringes after use.
- 7. A participant requiring documentation of their participation in the program should contact the provider that enrolled them. That provider should contact the Harm Reduction Program who will then provide such documentation to the participant once enrollment is verified. Questions by authorities and/or legal counsel may be directed to the Harm Reduction Program.
- C. Participants should be offered up to 30 new syringes upon enrollment, as well as other available supplies. In most cases, a provider should let the participant take as many of the additional supplies they feel is necessary to prevent any sharing of injection equipment, or other risky behavior, *within reason.* A participant who is identified as having a problem with limits should have a provider ask them what they need, and the provider should get the items together for the individual.
  - If upon initial enrollment a participant has syringes to exchange, those should be added to the 30 offered upon enrollment.
- D. The encounter must be documented on the SEP Daily Exchange Log Form (referred to as the Log Form). The SEP Interview Form does not document the exchange itself. Enrollment in the program is noted on the Log Form in the "1st Visit" box.
- E. Appropriate referrals and services, if any, should then be initiated for the client.
- F. File the intake survey in a secure location this may be used in future visits to confirm the enrollment of an individual should they not have their SHARPS Card available.

# 8. Syringe Exchange Visits

Following their initial enrollment, SEP participants may present as needed (within the program's scheduled times) for harm reduction services. A visit shall include the following components:

- A. Promptly greeting and serving the client. If a delay is expected, this should be explained to the client.
- B. Provide the appropriate harm reduction services in an environment that protects client confidentiality while maintaining provider safety.

- C. Use the client's yellow SHARPS Card to confirm the client's prior enrollment and their participant code. In the event that a participant needs a replacement SHARPS Card before the one year expiration date, the program can use the client interview form on file to provide it without having to reinterview the participant while maintaining the correct expiration date.
- D. Obtain a count of the number of syringes being exchanged. This may be reported by the participant or an estimate based on the size of the container (however, do not remove syringes from a container to count). Do NOT handle sharps that are not in an appropriate container. If the client has no or few syringes to exchange, then a limited number may be provided (e.g., 10) the client should be encouraged to bring back used syringes to exchange.
- E. Have the client place the used syringes in the approved local sharps container.
- F. A provider should let the participant take as many of the additional supplies (e.g., cookers, twist ties, sterile cottons, sterile water and saline, alcohol pads, tourniquets, various sharps containers) that is necessary to prevent any sharing of injection equipment, or other risky behavior, within reason. A participant who is identified as having a problem with limits should have a provider ask them what they need, and the provider should get the items together for the individual.
- G. The encounter must be documented on the Log Form. Information that must be recorded includes:
  - the SHARPS Card ID of SEP client;
  - whether the visit is for a new enrollee, or the participant was reenrolled into the program based upon the annual expiration;
  - the number of used syringes brought in for exchange;
  - the number of program syringes issued to the participant;
  - the number of people, including the participant, who will receive needles from the exchange ("secondary exchange");
  - whether HIV/hepatitis screening, results, or vaccines are provided (do not record the actual test result);
  - referrals provided;
  - written participant complaints about a syringe exchange; and,
  - if syringes are provided to a participant who did not bring any to exchange, the reason for the provision should be written in the "comments" box.
- H. Appropriate referrals and services, if any, should then be initiated for the client.
- I. Have available and provide risk-reduction materials and condoms for syringe program participants to increase the safety of sexual activity. Staff should be available to answer questions concerning sex and the risks associated with sex and substance use/abuse.
- J. Provide, or have available, educational resources for program participants about safer injection practices, vein care, and related health issues to assist participants in reducing injection related complications. This includes abscess care and reducing the long term health consequences of the drugs themselves.

K. Ensure that the client has their SHARPS Card when they leave an exchange site with syringes and/or supplies. Both the participant and the provider may be liable for possession/distribution of paraphernalia if a participant is stopped by law enforcement after leaving the site if they cannot demonstrate their participation in the program. Participants must be instructed to identify themselves to law enforcement personnel as program participants in the event they have an encounter that results in a search of either themselves or their property. They should then disclose the location of the syringes so an officer is not injured. This often results in a more positive interaction between the participant and the officer(s).

#### 9. Re-Enrollment

When a participant 's card is expired, or they have not participated with the program for an extended period of time (over one year), the individual should be re-surveyed using the SEP Interview Form. The questions are identical, except for question 9 (which asks about other services being accessed through the SEP).

Providers should keep a log of these SHARPS Card ID codes with their other enrollments so a replacement card may be issued based on the original expiration date. These surveys are noted on the Log Form as the "Re-Survey" box.

# **References/Companion Manual**

- HIV Prevention Protocol
- Adult Viral Hepatitis Protocol
- Statewide Comprehensive Strategic Health Plan
- "Getting Off Right" The Harm Reduction Coalition
- "Safe Injection, Better Vein Care" video Albuquerque Health Care for the Homeless

#### **Attachments**

- The Harm Reduction Act
- SEP Regulations
- SEP Interview Form
- Log Form
- SHARPS Card template
- Provider Certification Training hand out
- Provider Certification and ID Card
- SEP Waste Management Protocol
- State Environment Dept. Solid Waste Management Infectious Waste Regulations 706 through 712 (pages 88 – 100)
- Law Enforcement Needle Stick Protocol Card template
- Law Enforcement Education training hand out

# 2) OVERDOSE PREVENTION TRAINING PROGRAM

# Background

Respiratory depression and arrest is the primary cause of death due to an opioid overdose. Naloxone is a specific opioid antagonist drug that rapidly reverses the effects of opiate drugs, including heroin. Naloxone may be effective in reversing an opioid/heroin overdose death if administered no more than three to five minutes after the person who has overdosed has stopped breathing. Naloxone should be viewed as one of several tools and skills that can be taught and employed to prevent an opioid/heroin overdose death.

New Mexico Department of Health (NMDOH) establishes guidelines for the dispensing of naloxone through NMDOH Public Health Offices (PHO) and Contractors in order to reduce fatal opioid overdose as established in Chapter 24, Article 23, Sections 24-23-1 and 24-23-2, NMSA 1978, and 7.32.7.1 through 7.32.13 NMAC, 9/13/2001.

NMDOH provides naloxone through the Opioid Antagonist Administration Program (OAAP), which is a component of an Overdose Prevention Training Program (OPTP) model developed in each Region under Central Office (Infectious Disease Bureau) guidance to prepare participants or Trained Targeted Responders. The OPTP was established to improve the response to drug overdoses, in order to prevent unnecessary loss of life. The program provides overdose education, including training on the administration of naloxone. While opioid antagonist administration does not automatically guarantee a reversal of the effects of opioid overdose, it is the only definitive care currently available. In addition, the training of injection drug users and their peers to prevent, and/or properly respond, to an overdose leads these peer educators within drug using communities to decrease overdose deaths by spreading prevention education.

#### **Service Population**

New Mexico State Law authorizes persons other than licensed health care professionals to administer the opioid antagonist naloxone to another person if: (1) he/she, in good faith, believes the other person is experiencing an opioid drug overdose; and (2) he/she acts with reasonable care in administering the drug to the other person. Individuals who have participated in a NMDOH-sanctioned OPTP are eligible to receive naloxone from a local Public Health Office — these individuals will hereafter be referred to as "participants".

This Protocol addresses the content and operations of an OPTP, including the provision of naloxone by employees and contractors of NMDOH to non-medical lay persons. A separate protocol has been developed for external entities contracted to provide OPTP services and should be consulted as needed.

#### Methodology

Overdose Prevention Training teaches strategies for reducing the likelihood of overdose, the importance of providing rescue breathing to a person who is overdosing, the importance of quickly contacting professional medical help in the event of an

overdose, and the appropriate use of naloxone to reverse the effects of opiate overdose. One component of OPTP may include the provision of naloxone (through an OAAP) to participants.

This protocol incorporates a Standing Order for NMDOH nursing staff (including contractors) to dispense naloxone to enrolled clients without the need of an individual prescription (or verbal order) from a provider – see below.

# 1. Implementation and General Provisions

# Personnel

A Program Director shall be identified in each Region who manages the OPTP. The Program Director shall:

- 1. Provide evidence of coordination of the OAAP with local Emergency Medical Services and emergency dispatch agencies, including 911 dispatch agencies;
- 2. Develop processes to ensure that the naloxone is maintained and stored by NMDOH prior to distribution in accordance with the manufacturer's guidelines and NMDOH policy/procedures.
- 3. Provide direction in the selection of program participants;
- 4. Develop processes to ensure that all program participants have been trained by an NMDOH–Harm Reduction Program-approved OPTP;
- 5. Maintain naloxone administration training records for all program participants while they are active in the program, and for a least three (3) years thereafter;
- 6. Maintain OAAP records including naloxone inventory records, program participant training records, and OPTP usage records;
- 7. Ensure that all administrations of naloxone are reported to the Harm Reduction Program using the required format; and,
- 8. Assist the Physician Medical Director with quality assurance review of all naloxone administrations.

The Regional Health Officer (RHO), or other designated NMDOH physician shall be the **Physician Medical Director** for the regional OAAP (note: this may include physicians who are not located within the Region, such as RHO's in other Regions). The Physician Medical Director provides oversight of the program in accordance with the requirements of the New Mexico Board of Pharmacy (NMBOP). The selected physician shall:

- 1. Provide medical leadership, expertise, and oversight of the program;
- 2. Serve as an advocate and spokesperson for the OAAP;
- 3. Serve as the prescribing clinician for the dispensing of naloxone, or identify another NMDOH clinician to serve in this role;
- 4. Ensure that all program participants are properly trained and their skills are maintained;
- 5. Ensure quality assurance review for all administrations of naloxone;
- Assume overall responsibility for how the OAAP is planned and conducted; and,
- 7. Ensure compliance with the NMBOP requirements for the issuance, control, and storage of medications.

As the Public Health Division of the Department of Health has a centralized **State Pharmacy** and **Pharmacy Director** who provides oversight and maintains the ordering, inventory, and shipping of supplies and medications, including naloxone, to Public Health Offices and the programs they support, for the purposes of the OAAP the NMDOH Pharmacy Director will serve as the **Consulting Pharmacist**.

Each PHO usually assigns one **Nurse** to be responsible for the duties of the Pharmacy Director for that location and who is responsible for the naloxone provided through the State Pharmacy. Both the Program Director and the Physician Medical Director shall work with the Nurse who represents the PHO State Pharmacy representative to ensure program functions.

# **Applicability**

This protocol applies to all NMDOH employees and contract providers who are certified to provide overdose prevention training with naloxone prescription to both current and former injection drug users, their family members and friends, treatment providers, and other non-medical first responders, such as law enforcement personnel, who may encounter an overdose situation while performing their duties.

A separate protocol has been developed for external entities (i.e., non-NMDOH staff) contracted to provide these services and should be consulted as needed.

#### Responsibility

NMDOH leadership has the ultimate responsibility for assuring this policy is enforced and has the ultimate authority to accept or reject the recommendations of the Harm Reduction Program. The Harm Reduction Program is responsible for monitoring, reviewing and certifying both local public health OPTP and contracted providers and the quality of the training being provided.

#### 2. Program Operation

#### Registration of an Overdose Prevention Program

All Local Health Offices are registered as Overdose Prevention Program sites.

#### **EMS Notification**

Local EMS agencies shall be notified of the activation and existence of the OPTP. The notification shall include the name of the OPTP Program Director, Physician Medical Director, location of the program, telephone number, and a copy of medical director approved protocols. The local EMS agencies shall also be notified if an existing OPTP stops or is cancelled.

#### **Opioid Antagonist Selection**

OAAP shall use naloxone as the opioid antagonist. The administration device to be used is the 2 ml prefilled dose with an atomizer for intranasal delivery.

#### Response Supplies

OPTP shall provide and maintain at least the following minimum response equipment as selected by the Physician Medical Director:

- 1. Medical exam gloves.
- 2. Container approved for sharp medical waste.
- 3. Mask or other barrier for use during rescue breathing.

#### Medication Storage and Control

Medication storage and control shall be in accordance with manufacturer's recommendations, the NMBOP, and the Federal Food and Drug Administration (FDA) rules and regulations.

#### 3. Required Documentation

The OPTP shall establish and maintain a record keeping system that is available for audit. It shall include the following information:

- 1. List of program participants;
- 2. Dates of training for program participants;
- 3. Copy of Physician Medical Director approved medical protocols;
- 4. Copy of registration and EMS service notification forms;
- 5. Naloxone Administration usage reports/Data collection forms;
- 6. Quality assurance review documentation; and,
- 7. Naloxone order and maintenance records.

"Narcan Enrollment/Record of Use Forms" should be sent by the OPTP staff to the Harm Reduction Program in Santa Fe.

#### 4. Enrollment

#### Overdose Prevention Training

To enroll in the program, participants must have been trained in overdose prevention (+/- naloxone administration) by an individual approved by the NMDOH Harm Reduction Program to provide such training. The overdose prevention training for participants includes what is and what causes an overdose, how overdoses can be avoided, how to identify and properly respond to an opioid overdose, universal safety precautions, rescue breathing, activating EMS, and the administration of naloxone. While opioid antagonist administration does not automatically guarantee a reversal of the effects of opioid overdose, it is the only definitive care currently available. In addition, the training of injection drug users and their peers to prevent, and/or properly respond, to an overdose leads these peer educators within drug using communities to decrease overdose deaths by spreading prevention education.

Training of a participant for the use of naloxone includes:

- 1. A discussion of the indications, contraindications, potential adverse reactions, and administration of the medication.
- 2. A discussion of logistic considerations, such as storage in a relatively stable environment, avoiding direct sunlight or excessive freezing or heat.
- Information regarding the expiration date of the medication and instruction to the participant to discard the prescribed medication and return for a new supply before the currently prescribed syringes expires, and not to use the drug if the solution is cloudy.

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Every person who receives overdose prevention training and/or is prescribed and provided with naloxone will have a Narcan Enrollment/Record of Use Form completed and signed by the trainer that will be sent to the Harm Reduction Program in Santa Fe by the 10<sup>th</sup> of every month. Only forms for participants who have actually received naloxone or reported an overdose reversal should be submitted. The report form shall be designated by the NMDOH Harm Reduction Program, and shall include at a minimum:

- 1. Name of the OAAP;
- 2. Name of the trainer submitting the report;
- 3. Unique participant code of the participant;
- 4. If reporting the use of naloxone:
- 5. Approximate date of naloxone use;
- 6. Amount of naloxone administered:
- 7. Amount of naloxone replaced to the participant at the time of the report;
- 8. If known, list the type of drugs (other than opioids) taken by the person to whom the naloxone was administered; and,
- 9. Circumstances relating to overdose (if known):
- 10. Was EMS called, and if not, why;
- 11. Was the person transported to a clinical facility;
- 12. Was rescue breathing performed on the person who overdosed;
- 13. Distance from nearest emergency department (in road miles);
- 14. Clinical disposition of the incident (if known).

During enrollment, a chart will also be created in the NMDOH electronic medical record (BEHR) that includes (at least) the minimum elements of a medical record: the name and date of birth of the participant; participant allergies (or no known allergies); the medical indication for the prescription of naloxone; and documentation that the participant has completed overdose prevention training that is approved by the Harm Reduction Program, and been informed and understands the indications, contraindications, potential adverse reactions, and proper administration of the drug. The Narcan Enrollment/Record of Use form may be scanned into the medical record.

The participant will then receive a "Narcan Card" and supply of medication.

#### **Enrollment Cards**

It is preferred to avoid having a trained participant obtain their naloxone by referral. In certain cases, such as a training provided in a detention facility, or in rural areas, where it is not possible to provide the naloxone to a participant at the time of the training, an enrollment card should be given to the participant, along with information on suggested locations where the participant may redeem the card for their naloxone and related equipment. When the card is redeemed, the original trainer should then send in the participant's enrollment form. This card should have:

- 1. The individuals unique participant code;
- 2. The date and location of the training; and
- 3. The name and telephone number of the trainer (or the OAAP).

#### Naloxone Prescription and Dispensing

Naloxone (trade name: Narcan) is a prescription medication, not a DEA-scheduled drug. Naloxone is on the PHD Pharmacy dispensing formulary. NMDOH personnel with independent prescribing authority as defined by the NMBOP (e.g., physicians, Nurse Practitioners, Physician Assistants) are authorized to prescribe naloxone to opiate users in the context of NMDOH-sanctioned overdose prevention and treatment education programs. A naloxone prescription (or the medication itself) may be provided directly to the opiate user, family members, friends, or domestic partners of the active opiate user for the purpose of ensuring greater community access and decreasing opiate overdose fatalities statewide. The New Mexico Board of Pharmacy (NMBOP) requires that a naloxone prescription specify:

- 1. The name of the individual to whom the medication is prescribed;
- 2. The name of the clinician with the authority to prescribe the medication;
- 3. An entry into the medical record that defines the prescribing event and the medical indications for the prescription.

Of note, an NMDOH clinician with independent prescribing authority could, theoretically, provide a prescription to obtain naloxone from an external pharmacy to anyone (whether enrolled in the program or not). However, only participants in the program may be prescribed and provided with naloxone from NMDOH dispensing site supplies.

Each NMDOH OPTP will have an NMDOH clinician authorized to prescribe naloxone, referred to as the "**prescribing clinician**". The prescribing clinician's function for the program is to serve as the clinician of record for standing orders.

Both medical (e.g., nurses, nurse practitioners, physician assistants, physicians) and non-medical staff (e.g., Disease Prevention Specialists, Health Educators) may be trained and approved to provide education on overdose and naloxone administration to participants using NMDOH Harm Reduction Program guidelines and best practices. However, only those individuals who have authority to dispense medications may provide naloxone to participants under the authority of the prescribing clinician. As a result, staff providing services within an NMDOH-sanctioned OPTP may be able to a) only provide the overdose prevention education/visit component (e.g., 'trained' DPS), b) only be able to dispense medication (e.g., 'untrained' nurse or physician), or c) may be able to do both (e.g., 'trained' nurse).

#### 5. Naloxone Dispensing Visits

The process for clients receiving naloxone includes:

1. The participant can present to a local health office that provides naloxone and present their "Narcan Card". If the client does not have a "Narcan Card," their unique identifier number can be found by calling the Harm Reduction Program in Santa Fe to confirm training if necessary. The unique identifier number consists of the first letter of the first name, first two letters of the last name, and their date of birth using six digits (first two for month, second two for day, and last two digits of year) Note: this step has already been completed if the dispensing occurs immediately following participation in training.

- 2. A Narcan Enrollment/Record of Use Form will be completed for the client.
- 3. Document the participant contact in BEHR. Should BEHR be unavailable at the time of the provision of service (e.g., power outage, outreach) or the staff person does not have BEHR access, then use BEHR-down processes see <a href="http://intranet/PHD/behr.html">http://intranet/PHD/behr.html</a> and <a href="http://intranet/PHD/clinicalForms.html">http://intranet/PHD/clinicalForms.html</a>. Record the encounter in BEHR as soon as possible these forms may be destroyed once entry into BEHR has been completed.
- 4. Under the Naloxone Standing Order (see below), an individual with dispensing authority will provide two (2) pre-filled syringes of naloxone for intranasal use (2 mg in 2cc) and a Mucosal Atomization Device (MAD) using DOH pharmacy signout procedure. Each box containing naloxone must be labeled with an NMDOH Pharmacy label indicating the name of the participant, the name of the prescribing clinician, the date, and instructions for the use of the medication.

More doses may be provided depending on the conditions indicated by the participant, such as lengthy travel or limited hours of availability.

The nurse or clinician dispensing the medication should remind the client about the expiration date of the medication and instruct the client to return for a new prescription before the currently prescribed Naloxone expires, and not to use the drug if the solution is cloudy. Naloxone should be stored in a relatively stable environment, avoiding direct sunlight or excessive freezing or heat.

#### References

None

#### **Attachments**

- Narcan Enrollment/Record of Use Form
- Enrollment Card (sample)
- Naloxone Orders (ordering form)
- Naloxone/Narcan Instructions
- Naloxone Drug Information Sheet (DIS) English and Spanish available at http://intranet/PHD/PharmacyDIS.html
- BEHR Down Forms available at http://intranet/PHD/clinicalForms.html

#### **Additional Resources**

- NC Project Lazarus http://projectlazarus.org/patients-families/videos
- Southwest Pathways http://www.health.state.nm.us/phd/dist3/pathways.htm

#### NALOXONE STANDING ORDERS

#### Introduction

Public Health Offices where Overdose Prevention Training Program (OPTP) services are provided should be able to dispense naloxone even if a clinician is not available. This standing order enables NMDOH nursing staff to dispense naloxone to OPTP clients.

A client is an individual who is enrolled in the OPTP program, which includes formal training in naloxone use from an NMDOH Harm Reduction Program-approved trainer.

#### Order:

- 1. The client must either possess an NMDOH "Narcan card" with their name on it or their name can be found in the files or data base used by the OPTP. Call the Harm Reduction Program Manager in Santa Fe to confirm training if necessary.
- 2. Using BEHR HR (Narcan) template, update the record, including the Reason for Visit, HPI (History of Present Illness), PMH (Past Medical History), Family Hx (Family History), and Personal Hx (Personal History). This includes:
  - If one or more doses of naloxone have been previously dispensed to the client, and if so, the status of the medication (e.g., expired, lost, administered).
  - If one or more doses have been administered by or to the client, document this in the BEHR note and complete a "Narcan Enrollment/Record of Use" form with the client for each use this form is faxed by to the Harm Reduction Program Manager in Santa Fe (the fax number is on the bottom of the form).
  - Document any problems with administration (e.g., allergic reaction, pulmonary edema).

If BEHR is not available (e.g., during an outreach) use the then use BEHR-down processes – see <a href="http://intranet/PHD/behr.html">http://intranet/PHD/clinicalForms.html</a>. Record the encounter in BEHR as soon as possible - these forms may be destroyed once entry into BEHR has been completed.

- 3. If there are no new medical contraindications or prior problems with use of naloxone, and the client requests additional doses, dispense two (2) pre-filled syringes of naloxone (2mg in 2cc) for intranasal use and a Mucosal Atomization Device (MAD) using DOH pharmacy sign-out procedures (i.e., each box must be labeled with a NMDOH Pharmacy label indicating the name of the participant, the name of the prescribing clinician, the date, and the instruction for the use of the medication). Note that more doses may be provided depending on the conditions indicated by the participant, such as lengthy travel or limited hours of availability.
- 4. Provide a drug information sheet with the medication (http://intranet/PHD/PharmacyDIS.html).

PLEASE see the NMDOH Harm Reduction Protocol at <a href="http://intranet/PHD/clinical\_protocols.html">http://intranet/PHD/clinical\_protocols.html</a> for further recommendations and requirements regarding medication administration including enrollment procedures.

For any issues not covered by this order, please contact the Regional Health Officer or other designated prescribing clinician for further guidance.

Please place this standing order with your Harm Reduction AND your Standing Orders Notebook.

Prescribing C	Clinician Name:	 	
_			
Signature: _		 	
Data			
Date:			

#### 3) **DEFINITIONS**

- 1. "Administration of Opioid Antagonist" means the administration of an opioid antagonist by a person authorized pursuant to Regulation.
- 2. "Emergency Medical Service (EMS)" means the services rendered by licensed Emergency Medical Technicians, certified Emergency Medical Services First Responders or Emergency Medical Dispatchers in response to a person's need for immediate medical care to prevent loss of life or aggravation of physical or psychological illness or injury.
- 3. "**Medical Direction**" means guidance or supervision for trained targeted responders provided by a physician for the administration of opioid antagonists. This includes overseeing training, emergency medical services coordination, protocol approval, quality assurance, and reporting.
- 4. "Opioid" means containing or derived from opium, including but not limited to morphine, heroin, or pharmaceutical medications containing opiates, such as methadone, codeine, hydrocodone, and oxycontin.
- 5. "Opioid antagonist" means a drug that nullifies in whole or in part the administration of an opioid. The opioid antagonist is limited to naloxone or other medications approved by the NMDOH, unless otherwise stated in this regulation. The administered dose for suspected overdose in an adult is initially 0.4mg-2.0mg IV initially (0.01mg/kg body weight for children), and may be repeated at 2-3 minute intervals to a maximum of 10mg (a single dose of 0.1 mg/kg body weight for children). If an I.V. route of administration is not available, naloxone may be administered I.M. or S.C. in divided doses. For intranasal administration, the dose is 2mg IN (1mg/ml per nostril using an mucosal atomization device).
- 6. "Opioid Antagonist Administration Program (OAAP)" means an organized program to administer naloxone in accordance with these regulations.
- 7. "Overdose Prevention Training Program" means a training program which teaches overdose prevention information and practices, and prepares a person to administer an opioid antagonist as recommended by the Department of Health for an OAAP.
- 8. "Participant" is any qualified individual who has been trained and enrolled in the program.
- "Physician" means a doctor of medicine or doctor of osteopathy who is licensed or otherwise authorized to practice medicine or osteopathic medicine in New Mexico.
- 10. "Physician Medical Director" means a physician who is responsible for oversight of an Opioid Antagonist Administration Program, including providing for or ensuring the medical control of trained targeted responders; the development, implementation, and evaluation of medical protocols; oversight of quality assurance activities, and compliance with the NMBOP requirements.
- 11. "**Protocols**" means predetermined, written medical care plans and includes standing orders.
- 12. "Provider" means a person or entity contracted to deliver services.

13. "Trained Targeted Responder (TTR)" means a person who has completed an authorized opioid antagonist training program and who administers opioid antagonists as defined in Harm Reduction Protocols.

#### 4) ATTACHMENTS

**Attachment A:** Clinical Protocol/Manual Approval Sheet **Attachment B:** Acknowledgement and Receipt of New/Revised Clinical Protocol

### PUBLIC HEALTH DIVISION CLINICAL PROTOCOL/MANUAL APPROVAL SHEET

PROGRAM: Public Health Division - Harm Reduction

CLINICAL PROTOCOL/MANUAL TITLE: Harm Reduction Services

Reviewed by:	
Name: Supplement Hunger	Date: 1-30-12
Name:	Date:
Program Manager:	Date: 1/30/12
Bureau Chief: Gayle Kenny Sayle M. Kenny	Date: 1/36/12
Bureau Medical Director: Linda Gorgos, MD	Date: (/27/12_
PHD Medical Director: Maggi Gallaher, MD	Date: 1/2-7/12
Regional Health Officer:	Date:
PHD Chief Nurse:	Date:

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## PUBLIC HEALTH DIVISION ACKNOWLEDGEMENT AND RECEIPT OF NEW/REVISED CLINICAL PROTOCOL

PROGRAM:				
CLINICAL PROTO	COL/MANUAL TITLE	E: <u>Harm Red</u>	luction Services	<u>3</u>
I have reviewed the	e document listed abo	ve and I app	rove it for prac	tice in Region 2.
Regional Director		Date		
Regional Health Officer		Date		
Director of Nursing Service		Date		
Director of Nursing Service			Date	
I have received, re	viewed and will follow	this Clinical	Protocol and its	s Standing Orders.
Staff (Clinicians, Pl	HNs, DPSs, etc.):			
Name	Date	Name		Date
Name	Date	Name		Date
Name	Date	Name		Date
Name	Date	Name		Date
Name	Date	Name		Date
Name	Date	Name		Date
Name	Date	Name		Date
 Name	 Date	Name		Date

#### **New Mexico Overdose Prevention Laws**

#### 24-23-1 NMSA 1978. Authority to administer opioid antagonists; release from liability.

- A. A person authorized under federal, state or local government regulations, other than a licensed health care professional permitted by law to administer an opioid antagonist, may administer an opioid antagonist to another person if:
- (1) he, in good faith, believes the other person is experiencing a drug ; and
- (2) he acts with reasonable care in administering the drug to the other person.
- B. A person who administers an opioid antagonist to another person pursuant to Subsection A of this section shall not be subject to civil liability or criminal prosecution as a result of the administration of the drug.

History: Laws 2001, ch. 228, § 1.

#### New Mexico 911 Good Samaritan Law

#### 30-31-27.1 NMSA 1978 Overdose prevention; limited immunity.

- A. A person who, in good faith, seeks medical assistance for someone experiencing a drug-related overdose shall not be charged or prosecuted for possession of a controlled substance pursuant to the provisions of Section 30-31-23 NMSA 1978 if the evidence for the charge of possession of a controlled substance was gained as a result of the seeking of medical assistance.
- B. A person who experiences a drug-related overdose and is in need of medical assistance shall not be charged or prosecuted for possession of a controlled substance pursuant to the provisions of Section 30-31-23 NMSA 1978 if the evidence for the charge of possession of a controlled substance was gained as a result of the overdose and the need for medical assistance.
- C. The act of seeking medical assistance for someone who is experiencing a drug-related overdose may be used as a mitigating factor in a criminal prosecution pursuant to the Controlled Substances Act.

History: Laws 2007, ch. 260, § 1.

#### **Controlled Substances Act (Excerpt pertaining to Harm Reduction)**

#### 30-31-23 NMSA 1978 Controlled substances; possession prohibited.

- A. It is unlawful for a person intentionally to possess a controlled substance unless the substance was obtained pursuant to a valid prescription or order of a practitioner while acting in the course of professional practice or except as otherwise authorized by the Controlled Substances Act. It is unlawful for a person intentionally to possess a controlled substance analog.
- B. A person who violates this section with respect to:
- (1) one ounce or less of marijuana or synthetic cannabinoids is, for the first offense, guilty of a petty misdemeanor and shall be punished by a fine of not less than fifty dollars (\$50.00) or more

than one hundred dollars (\$100) and by imprisonment for not more than fifteen days, and, for the second and subsequent offenses, guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) or more than one thousand dollars (\$1,000) or by imprisonment for a definite term less than one year, or both;

- (2) more than one ounce and less than eight ounces of marijuana or synthetic cannabinoids is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) or more than one thousand dollars (\$1,000) or by imprisonment for a definite term less than one year, or both; or
- (3) eight ounces or more of marijuana or synthetic cannabinoids is guilty of a fourth degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978.
- C. A minor who violates this section with respect to the substances listed in this subsection is guilty of a petty misdemeanor and, notwithstanding the provisions of Sections 32A-1-5 and 32A-2-19 NMSA 1978, shall be punished by a fine not to exceed one hundred dollars (\$100) or forty-eight hours of community service. For the third or subsequent violation by a minor of this section with respect to those substances, the provisions of Section 32A-2-19 NMSA 1978 shall govern punishment of the minor. As used in this subsection, "minor" means a person who is less than eighteen years of age. The provisions of this subsection apply to the following substances:
- (1) synthetic cannabinoids;
- (2) any of the substances listed in Paragraphs (20) through (25) of Subsection C of Section <u>30-31-6</u> NMSA 1978; or
- (3) a substance added to Schedule I by a rule of the board adopted on or after the effective date of this 2011 act if the board determines that the pharmacological effect of the substance, the risk to the public health by abuse of the substance and the potential of the substance to produce psychic or physiological dependence liability is similar to the substances described in Paragraph (1) or (2) of this subsection.
- D. Except for those substances listed in Subsection E of this section, a person who violates this section with respect to any amount of any controlled substance enumerated in Schedule I, II, III or IV or a controlled substance analog of a substance enumerated in Schedule I, II, III or IV is guilty of a misdemeanor and shall be punished by a fine of not less than five hundred dollars (\$500) or more than one thousand dollars (\$1,000) or by imprisonment for a definite term less than one year, or both.
- E. A person who violates this section with respect to phencyclidine as enumerated in Schedule III or a controlled substance analog of phencyclidine; methamphetamine, its salts, isomers or salts of isomers as enumerated in Schedule II or a controlled substance analog of methamphetamine, its salts, isomers or salts of isomers; flunitrazepam, its salts, isomers or salts

of isomers as enumerated in Schedule I or a controlled substance analog of flunitrazepam, including naturally occurring metabolites, its salts, isomers or salts of isomers; gamma hydroxybutyric acid and any chemical compound that is metabolically converted to gamma hydroxybutyric acid, its salts, isomers or salts of isomers as enumerated in Schedule I or a controlled substance analog of gamma hydroxybutyric acid, its salts, isomers or salts of isomers; gamma butyrolactone and any chemical compound that is metabolically converted to gamma hydroxybutyric acid, its salts, isomers or salts of isomers as enumerated in Schedule I or a controlled substance analog of gamma butyrolactone, its salts, isomers or salts of isomers; 1-4 butane diol and any chemical compound that is metabolically converted to gamma hydroxybutyric acid, its salts, isomers or salts of isomers as enumerated in Schedule I or a controlled substance analog of 1-4 butane diol, its salts, isomers or salts of isomers; or a narcotic drug enumerated in Schedule I or II or a controlled substance analog of a narcotic drug enumerated in Schedule I or II is guilty of a fourth degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978.

- F. Except for a minor as defined in Subsection C of this section, a person who violates Subsection A of this section while within a posted drug-free school zone, excluding private property residentially zoned or used primarily as a residence and excluding a person in or on a motor vehicle in transit through the posted drug-free school zone, with respect to:
- (1) one ounce or less of marijuana or synthetic cannabinoids is, for the first offense, guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) or more than one thousand dollars (\$1,000) or by imprisonment for a definite term less than one year, or both, and for the second or subsequent offense, is guilty of a fourth degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978;
- (2) more than one ounce and less than eight ounces of marijuana or synthetic cannabinoids is guilty of a fourth degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978;
- (3) eight ounces or more of marijuana or synthetic cannabinoids is guilty of a third degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978;
- (4) any amount of any other controlled substance enumerated in Schedule I, II, III or IV or a controlled substance analog of a substance enumerated in Schedule I, II, III or IV, except phencyclidine as enumerated in Schedule III, a narcotic drug enumerated in Schedule I or II or a controlled substance analog of a narcotic drug enumerated in Schedule I or II, is guilty of a fourth degree felony and shall be sentenced pursuant to the provisions of Section 31-18-15 NMSA 1978; and
- (5) phencyclidine as enumerated in Schedule III, a narcotic drug enumerated in Schedule I or II, a controlled substance analog of phencyclidine or a controlled substance analog of a narcotic

drug enumerated in Schedule I or II is guilty of a third degree felony and shall be sentenced pursuant to the provisions of Section <u>31-18-15</u> NMSA 1978.

History: 1953 Comp., § 54-11-23, enacted by Laws 1972, ch. 84, § 23; 1974, ch. 9, § 4; 1980, ch. 23, § 4; 1983, ch. 183, § 1; 1987, ch. 68, § 5; 1989, ch. 123, § 1; 1990, ch. 19, § 5; 1990, ch. 33, § 1; 2005, ch. 280, § 7; 2011, ch. 16, § 3.

#### **New Mexico Overdose Regulations**

TITLE 7 HEALTH

CHAPTER 32 ALCOHOL AND DRUG ABUSE

PART 7 AUTHORIZATION TO ADMINISTER OPIOID ANTAGONISTS

**7.32.7.1 ISSUING AGENCY:** Department of Health; Public Health Division; Infectious Disease Prevention and Control Bureau. [7.32.7.1 NMAC - Rp, 7.32.7.1 NMAC, 9/13/2001]

**7.32.7.2 SCOPE:** This rule applies to all persons other than a licensed health care professional permitted by law to administer an opioid antagonist to another person, including opioid antagonist administration programs.

[7.32.7.2 NMAC - Rp 7.32.7.2 NMAC, 9/13/2001; A, 4/30/2009]

**7.32.7.3 STATUTORY AUTHORITY:** The statutory authority for adopting these rules is found in NMSA 1978, Section 9-7-6 E (Department of Health Act), which authorizes the Secretary of Health to "adopt such reasonable and procedural rules and regulations as may be necessary to carry out the duties of the department" and in NMSA 1978, Section 24-23-1 (Public Health Act), which allows a person "authorized by federal, state or local government regulations, other than a licensed health care professional permitted by law to administer an opioid antagonist" to administer an opioid antagonist to another person under certain circumstances. [7.32.7.3 NMAC - Rp 7.32.7.3 NMAC, 9/13/2001; A, 4/30/2009]

**7.32.7.4 DURATION:** Permanent. [7.32.7.4 NMAC - Rp, 7.32.7.4 NMAC, 9/13/2001]

**7.32.7.5 EFFECTIVE DATE:** September 13, 2001, unless a later date is cited at the end of a section.

[7.32.7.5 NMAC - Rp, 7.32.7.5 NMAC, 9/13/2001]

**7.32.7.6 OBJECTIVE:** The objective is to authorize persons, other than a licensed health care professional permitted by law to administer an opioid antagonist, to administer an opioid antagonist to another person if: (1) he, in good faith, believes the other person is experiencing an opioid drug overdose; and (2) he acts with reasonable care in administering the drug to the other person. Further, this regulation shall provide recommended guidelines to prevent opioid overdose death.

[7.32.7.6 NMAC - Rp, 7.32.7.6 NMAC, 9/13/2001]

#### **7.32.7.7 DEFINITIONS:**

- **A.** "Administration of opioid antagonist" means the administration of an opioid antagonist by a person authorized pursuant to this regulation.
  - **B.** "Department" means the New Mexico department of health.

- C. "Emergency medical service(s) (EMS)" means the services rendered by licensed emergency medical technicians, certified emergency medical services first responders or emergency medical dispatchers in response to a person's need for immediate medical care to prevent loss of life or aggravation of physical or psychological illness or injury.
- **D.** "Medical direction" means guidance or supervision for trained targeted responders provided by a physician for the administration of opioid antagonists. This includes overseeing training, emergency medical services coordination, protocol approval, quality assurance and reporting.
- **E.** "Opioid" means containing or derived from opium, including but not limited to morphine and heroin.
- **F.** "Opioid antagonist" means a drug that nullifies in whole or in part the administration of an opioid. The opioid antagonist is limited to naloxone or other medications approved by the department, unless otherwise stated in this regulation.
- **G.** "Opioid antagonist administration program" means an organized program to administer an opioid antagonist in accordance with these regulations.
- **H.** "Opioid antagonist training program" means a training program which prepares a person to administer an opioid antagonist as shown by best practices or recommended by the department for an opioid antagonist administration program.
- **I.** "Physician" means a doctor of medicine or doctor of osteopathy who is licensed or otherwise authorized to practice medicine or osteopathic medicine in New Mexico.
- **J.** "Physician medical director" means a physician who is responsible for medical oversight of an opioid antagonist administration program, including providing for or ensuring the medical control of trained targeted responders; developing, implementing, and evaluating medical protocols; overseeing quality assurance activities, and ensuring compliance with the New Mexico board of pharmacy requirements.
- **K.** "**Protocols**" means predetermined, written medical care plans and includes standing orders.
- **L.** "**Provider**" means a person or entity delivering emergency medical services in New Mexico.
- **M.** "Trained targeted responder" means a person who has completed an authorized opioid antagonist training program and who administers opioid antagonists. [7.32.7.7 NMAC Rp, 7.32.7.7 NMAC, 9/13/2001; A/E, 01/29/2009; A, 4/30/2009]

#### 7.32.7.8 INDIVIDUAL AUTHORIZATION TO ADMINISTER OPIOID

**ANTAGONIST:** A person, other than a licensed health care professional permitted by law to administer an opioid antagonist, is authorized to administer an opioid antagonist to another person if he, in good faith, believes the other person is experiencing an opioid drug overdose and he acts with reasonable care in administering the drug to the other person. It is strongly recommended that any person administering an opioid antagonist to another person immediately call for emergency medical services.

[7.32.7.8 NMAC - Rp, 7.32.7.8 NMAC, 9/13/2001; A, 4/30/2009]

#### 7.32.7.9 ESTABLISHMENT OF AN OPIOID ANTAGONIST

**ADMINISTRATION PROGRAM:** The primary reason for establishing an opioid antagonist administration program by trained targeted responders is to improve response to drug overdose, which may prevent unnecessary loss of life. While opioid antagonist administration does not

automatically guarantee to reverse the effects of overdose due to substance use, it is the only definitive care currently available for reversing the effects of opioid substances. Therefore, persons suffering from an overdose, when an opioid is a suspected substance, should be administered an opioid antagonist as quickly as possible.

[7.32.7.9 NMAC - N, 9/13/2001; A, 4/30/2009]

#### 7.32.7.10 OPIOID ANTAGONIST ADMINISTRATION PROGRAM GUIDELINES:

An opioid antagonist administration program shall adhere to the following guidelines.

- **A. Opioid antagonist administration program director:** A program director shall be identified who manages the opioid antagonist administration program. The program director shall:
- (1) identify a physician medical director to oversee the opioid antagonist administration program;
  - (2) select and identify persons as trained targeted responders;
- (3) maintain opioid antagonist administration training records for all trained targeted responders while they are active in the program, and for at least three (3) years thereafter;
- (4) maintain opioid antagonist administration program records, including opioid antagonist inventory records, trained targeted responder training records, and opioid antagonist administration program usage records;
- (5) ensure that all trained targeted responders are trained using an opioid antagonist training program, which may be recommended by the department;
- **(6)** provide evidence of coordination of the opioid antagonist administration program with local EMS, including 911 dispatch agencies;
- (7) register the opioid antagonist administration program with the department using the application format outlined in appendix A;
- (8) report all administrations of an opioid antagonist to the department using the reporting format outlined in appendix B;
- (9) assist the physician medical director with quality assurance review of all opioid antagonist administrations; and
- (10) ensure that the opioid antagonist is maintained and stored in accordance with the manufacturer's guidelines.
- **B. Physician medical director:** Each opioid antagonist administration program shall appoint and retain a physician medical director who provides oversight of the opioid antagonist administration program in accordance with the requirements of the New Mexico board of pharmacy. The selected physician shall:
  - (1) provide medical leadership, expertise, and medical oversight of the program;
- (2) serve as an advocate and spokesperson for the opioid antagonist administration program;
- (3) ensure that all trained targeted responders are properly trained and that trained targeted responders' skills are maintained;
- **(4)** develop and approve medical protocols for the opioid antagonist administration program;
  - (5) ensure quality assurance review for all administrations of an opioid antagonist;
- (6) assume overall responsibility for how the opioid antagonist administration program is planned and conducted; and
- (7) ensure compliance with the New Mexico board of pharmacy requirements for the issuance, control and storage of medications.

- **C. Trained targeted responders:** A trained targeted responder shall:
- (1) complete an initial opioid antagonist administration training program that is recommended by the department;
- (2) complete a department recommended refresher opioid antagonist administration training course at least once every two years;
- (3) activate the emergency medical system using pre-established methods (e.g., contact E-911 public safety answering point or local emergency number) during any response to a victim of suspected drug overdose, and advise local EMS that an opioid antagonist is being used;
- (4) comply with physician medical director protocols for response to victims of suspected drug overdose;
- (5) report all responses to suspected drug overdoses to the opioid antagonist administration program director and physician medical director and complete a report as detailed in appendix B; the trained targeted responder shall submit a copy of the report to the department by the 10th day of the month following the month in which the opioid antagonist was administered;
- (6) ensure that the opioid antagonist drugs and other supplies are maintained and used in accordance with the manufacturer's guidelines, and inspect the opioid antagonists' drug expiration dates at least monthly.
- **D. Notification:** The director of an opioid antagonist administration program shall promptly notify local EMS of the activation and existence of the opioid antagonist administration program. The notification shall include the name of the opioid antagonist administration's program director, physician medical director, location, telephone number, and a copy of medical director approved protocols. The director of an opioid antagonist administration program shall also promptly notify local EMS in the event that the opioid antagonist administration program stops or cancels its operations.

#### E. Opioid antagonist selection, supplies, and medication storage/control:

- (1) opioid antagonist selection: opioid antagonist administration programs shall use naloxone, or other medications approved by the department, as the opioid antagonist; the physician medical director shall select the specific administration device for the opioid antagonist.
- (2) response supplies: opioid antagonist administration programs shall provide and maintain at least the following minimum response equipment as selected by the physician medical director:
  - (a) medical exam gloves;
  - (b) container approved for sharp medical waste; and
  - (c) mask or other barrier for use during rescue breathing;
- (3) medication storage and control: medication storage and control shall be in accordance with the New Mexico board of pharmacy and federal food and drug administration rules and regulations.

[7.32.7.10 NMAC - N, 9/13/2001; A, 4/30/2009]

- **7.32.7.11 Record Keeping:** The opioid antagonist administration program shall establish and maintain a record keeping system that is available for audit by the department. It shall include the following information:
  - **A.** list of trained targeted responders;
  - **B.** dates of training for trained targeted responders;
  - **C.** copy of medical director approved medical protocols;
  - **D.** copy of the medical director contract/agreement;

- **E.** copy of registration and EMS notification forms;
- **F.** opioid antagonist administration usage reports/data collection forms (appendix B);
- **G.** quality assurance review documentation; and
- **H.** opioid antagonist purchase and maintenance records.

[7.32.7.11 NMAC - N, 9/13/2001; A, 4/30/2009]

#### 7.32.7.12 Appendix A: Registration of an opioid antagonist administration program:

Prior to beginning an opioid antagonist administration program, the program director shall submit an application for registration to the department using the following format:

- **A.** application date;
- **B.** program start-up date;
- **C.** program name;
- **D.** program director name;
- **E.** program mailing address;
- **F.** program physical location;
- **G.** program telephone number;
- **H.** physician medical director name;
- I. physician medical director mailing address;
- **J.** physician medical director telephone number;
- **K.** physician medical director New Mexico license number;
- **L.** date that the opioid antagonist administration program notified and coordinated with local emergency medical service(s), including emergency medical dispatch agencies, and the names and types of the services contacted;
  - M. name of consulting pharmacist;
  - N. address of consulting pharmacist;
  - **O.** telephone number of consulting pharmacist.

[7.32.7.12 NMAC - N, 9/13/2001; A, 4/30/2009]

- **7.32.7.13 Appendix B: Report of opioid antagonist administration:** Any administration of an opioid antagonist to another person by a trained targeted responder affiliated with an opioid antagonist administration program, shall be reported to the department. Any trained targeted responder who has knowledge of the administration of an opioid antagonist by a non-trained targeted responder shall also report such administration to the department. At a minimum, the report shall contain the following information:
  - **A.** name of opioid antagonist administration program;
  - **B.** name of trained targeted responder submitting report;
  - **C.** amount of opioid antagonist administered;
- **D.** if known, list the type of overdose drugs (other than opioids) taken by the person to whom the opioid antagonist was administered;
  - **E.** circumstances relating to overdose (if known);
  - **F.** date of overdose;
  - **G.** whether emergency medical services was called;
- **H.** whether the person to whom the opioid antagonist was administered was transported to a clinical facility;
- **I.** whether rescue breathing was performed on the person to whom the opioid antagonist was administered;

- **J.** distance from nearest emergency department (in road miles);
- **K.** clinical disposition of overdose incident (if known).

[7.32.7.13 NMAC - N, 9/13/2001; A, 4/30/2009]

#### History of 7.32.7 NMAC:

Pre - NMAC History: None.

#### **History of Repealed Material:**

7.32.7 NMAC, Authorization to Administer Opioid Antagonists, filed 06/01/2001.

# New Mexico Department of Health (NMDOH) Public Health Division (PHD) Protocol

## Overdose Prevention Training Protocol – External Programs November 2011

#### Background

Respiratory depression and arrest is the primary cause of death due to an opioid overdose. Naloxone is a specific opioid antagonist drug that rapidly reverses the effects of opiate drugs, including heroin. Naloxone may be effective in reversing an opioid/heroin overdose death if administered no more than three to five minutes after the person who has overdosed has stopped breathing. Naloxone should be viewed as one of several tools and skills that can be taught and employed to prevent an opioid/heroin overdose death.

New Mexico Department of Health (NMDOH) policy establishes guidelines for approved Opioid Antagonist Administration Programs (OAAP), which are a component of an Overdose Prevention Training Program (OPTP) model, to prepare participants or Trained Targeted Responders to respond to possible opioid overdoses, including the provision and administration of naloxone. The OPTP was established to improve response to drug overdose, in order to prevent unnecessary loss of life. The program provides overdose education (what is and what causes an overdose, how overdoses can be avoided, how to identify and properly respond to an opioid overdose, universal safety precautions, rescue breathing, activating EMS), including the administration of naloxone. While opioid antagonist administration does not automatically guarantee a reversal of the effects of opioid overdose, it is the only definitive care currently available. In addition, the training of injection drug users and their peers to prevent, and/or properly respond, to an overdose leads these peer educators within drug using communities to decrease overdose deaths by spreading prevention education.

#### **Service Population**

New Mexico State Law authorizes persons, other than licensed health care professionals, to administer the opioid antagonist naloxone to another person if: (1) he/she, in good faith, believes the other person is experiencing an opioid drug overdose; and (2) he/she acts with reasonable care in administering the drug to the other person. Individuals may be eligible to receive naloxone from sanctioned non-NMDOH OPTPs – these individuals will hereafter be referred to as the "participant".

This Protocol addresses the content and operations of an OPTP by employees and contractors of non-NMDOH agencies, for use by non-medical lay persons. This includes the provision of naloxone to Trained Targeted Responders (TTR), who are non-medical first responders (e.g., law enforcement or volunteer fire fighters), as they

may be the first to arrive at a medical emergency call, especially in rural areas of the state.

#### Methodology

Overdose Prevention Training teaches strategies for reducing the likelihood of overdose, the importance of providing rescue breathing to a person who is overdosing, the importance of quickly contacting professional medical help in the event of an overdose, and the appropriate use of naloxone to reverse the effects of opiate overdose. One component of OPTP may include the provision of naloxone (through an OAAP).

#### 1. Implementation and General Provisions

#### Personnel

A Program Director shall be identified by any entity who operates an OPTP. The Program Director shall:

- 1. Register the OAAP with the NMDOH using the application format;
- 2. Identify a Physician Medical Director to oversee each OAAP;
- 3. Provide evidence of coordination of the OAAP with local Emergency Medical Services and emergency dispatch agencies, including 911 dispatch agencies;
- 4. Ensure the naloxone is maintained and stored prior to distribution in accordance with the manufacturer's guidelines.
- 5. Select and identify program participants;
- 6. Ensure that all program participants are trained by an OPTP approved by the NMDOH Harm Reduction Program;
- 7. Maintain naloxone administration training records for all program participants while they are active in the program, and for a least three (3) years thereafter;
- 8. Maintain OAAP records including naloxone inventory records, program participant training records, and OPTP usage records;
- 9. Report all administrations of naloxone to the NMDOH using the required reporting format; and,
- 10. Assist the Physician Medical Director with quality assurance review of all naloxone administrations.

A **Physician Medical Director** shall be identified for each entity's OAAP who provides oversight of the program in accordance with the requirements of the New Mexico Board of Pharmacy (NMBOP). The selected physician shall:

- 1. Provide medical leadership, expertise, and oversee the program;
- 2. Serve as an advocate and spokesperson for the OAAP;
- 3. Serve as the prescribing physician for the dispensing of naloxone;
- 4. Ensure that all program participants are properly trained and their skills are maintained:
- 5. Develop and approve medical protocols for the OAAP;
- 6. Ensure quality assurance review for all administrations of naloxone;

- 7. Assume overall responsibility for how the OAAP is planned and conducted; and,
- 8. Ensure compliance with the NMBOP requirements for the issuance, control and storage of medications.

Each OPTP will identify a **Consulting Pharmacist** who will be responsible for maintaining the entity's licensure and compliance in accordance with NMBOP requirements for the ordering, inventory, issuance, control, and storage of medications.

Trained Targeted Responders: This is the title given to non-medical, emergency personnel who are trained to intervene in an overdose situation and allowed to carry and administer naloxone in the situation. This may include law enforcement, firefighters, some Emergency Medical Technicians, syringe exchange and outreach staff, and other non-medical personnel who may encounter an overdose situation while in performance of their duties. Such an effort has the same requirements as the other component of the OAAP (e.g., medical direction, a consulting pharmacist and a pharmacy where the medication may be stored in compliance with NMBOP). In this case, though, the Medical Director is responsible for:

- 1. Monitoring and updating responder training;
- 2. Checking the medication in and out of the pharmacy to the responders and monitoring compliance for care of the medication, and monitoring expiration dates:
- 3. Ensuring the activation of EMS during an overdose situation;
- 4. Ensuring the proper documentation of any performed intervention.

#### **Applicability**

This policy applies to all employees and contract providers of an entity certified to provide overdose prevention training with naloxone prescription to both current and former injection drug users, their family members and friends, treatment providers, and other non-medical first responders, such as law enforcement personnel, who may encounter an overdose situation while performing their duties.

#### Responsibility

The leadership of the entity maintaining the OPTP has the ultimate responsibility for assuring this policy is enforced and has the ultimate authority to accept or reject the recommendations of the Harm Reduction Program. The Harm Reduction Program is responsible for monitoring, reviewing and certifying OPTPs and the quality of the training being provided.

#### 2. Program Operation

#### Registration of an Overdose Prevention Program

Prior to beginning an OAAP, the Program Director shall submit an application for registration to the NMDOH using the format outlined below:

- 1. Application Date;
- Program Start-up Date;
- 3. Program Name;
- 4. Program Director Name;
- 5. Program Director E-mail Address;
- 6. Program Mailing Address;
- 7. Program Physical Location;
- 8. Program Telephone Number;
- 9. Physician Medical Director Name;
- 10. Physician Medical Director Mailing Address;
- 11. Physician Medical Director Telephone Number;
- 12. Physician Medical Director New Mexico License Number;
- 13. Notification to local EMS/911 Dispatch Agency Provide Date;
- 14. Name of Consulting Pharmacist;
- 15. Address of Consulting Pharmacist;
- 16. Telephone Number of Consulting Pharmacist.

#### **EMS Notification**

Local EMS agencies shall be notified of the activation and existence of the OAAP. The notification shall include the name of the OAAP Program Director, Physician Medical Director, location of the program, telephone number, and a copy of medical director approved protocols. The local EMS agencies shall also be notified if an existing OAAP stops or cancels the OPTP.

#### Opioid Antagonist Selection

OAAP shall use naloxone as the opioid antagonist. The Physician Medical Director shall select the specific injection or administration device. It is recommended that the 2 ml prefilled dose with an atomizer for intranasal delivery be used.

#### Response Supplies

OAAP shall provide and maintain at least the following minimum response equipment as selected by the Physician Medical Director:

- 1. Medical exam gloves.
- 2. Container approved for sharp medical waste.
- 3. Mask or other barrier for use during rescue breathing.
- 4. If an injectable delivery method is recommended, an agent to prepare skin before injection.

#### Medication Storage and Control

Medication storage and control shall be in accordance with the NMBOP and Federal Food and Drug Administration (FDA) rules and regulations.

#### 3. Required Documentation

The OAAP shall establish and maintain a record keeping system that is available for audit. It shall include the following information:

Harm Reduction Protocol for External Providers November 2011

- 1. List of program participants;
- Dates of training for program participants;
- 3. Copy of Physician Medical Director approved medical protocols;
- 4. Copy of the Physician Medical Director contract/agreement;
- 5. Copy of registration and EMS service notification forms;
- 6. Naloxone Administration usage reports/Data collection forms;
- 7. Quality assurance review documentation; and,
- 8. Naloxone purchase/order and maintenance records.

"Narcan Enrollment/Record of Use" forms should be sent by the PHN to the Harm Reduction Program in Santa Fe by the 10<sup>th</sup> of every month.

#### 4. Enrollment

Every person who receives overdose prevention training and/or is prescribed and provided with naloxone will have a Narcan Enrollment/Record of Use Form completed and signed by the trainer that will be sent to the Harm Reduction Program by the 10<sup>th</sup> of every month. Only forms for participants who have actually received naloxone or reported an overdose reversal should be submitted. The report form shall be designated by the NMDOH Harm Reduction Program, and shall include at a minimum:

- 1. Name of the OAAP;
- 2. Name of the trainer submitting the report;
- 3. Unique participant code of the participant;
- 4. If reporting the use of naloxone:
- 5. Approximate date of naloxone use;
- 6. Amount of naloxone administered;
- 7. Amount of naloxone replaced to the participant at the time of the report;
- 8. If known, list the type of drugs (other than opioids) taken by the person to whom the naloxone was administered; and,
- 9. Circumstances relating to overdose (if known):
- 10. Was EMS called, and if not, why;
- 11. Was the person transported to a clinical facility;
- 12. Was rescue breathing performed on the person who overdosed;
- 13. Distance from nearest emergency department (in road miles);
- 14. Clinical disposition of the incident (if known).

#### Enrollment Cards

It is preferred to avoid having a trained participant obtain their naloxone by referral. In certain cases, such as a training provided in a detention facility, or in rural areas, where it is not possible to provide the naloxone to a participant at the time of the training, an enrollment card should be given to the participant, along with information on suggested locations where the participant may redeem the card for their naloxone and related equipment. When the card is redeemed, the original trainer should then send in the participants enrollment form. This card should have:

1. The individuals unique participant code;

- 2. The date and location of the training; and
- 3. The name and telephone number of the trainer (or the OAAP).

#### TTR-Specific Training

As first responders, TTRs may have additional roles and responsibilities related to managing potential opioid overdoses. As a result, TTRs should:

- 1. Complete the initial OPTP recommended by the Department;
- 2. Every two (2) years, TTR's should complete a refresher OPTP from a NMDOH recommended training program;
- 3. Activate the EMS using pre-established methods (e.g. contact 911 public safety) during any response to a suspected overdose;
- 4. Comply with Physician Medical Director protocols for response to individuals experiencing a suspected overdose;
- 5. Report all responses to suspected overdose to the OAAP Program Director and Physician Medical Director and complete an enrollment/record of use report form report. A copy of the report shall be submitted to the Department by the 10<sup>th</sup> of each month;
- 6. Ensure that the opioid antagonist drugs and other supplies are maintained and used in accordance with the manufacturer's guidelines, and inspect the naloxone expiration date at least monthly.

#### Naloxone Training

Naloxone (trade name: Narcan) is a prescription medication, not a DEA-scheduled drug. Personnel with independent prescribing authority as defined by the NMBOP (e.g., Medical Doctors, Doctors of Osteopathy, Family Nurse Practitioners) are authorized to prescribe naloxone. A naloxone prescription (or the medication itself) may be provided directly to the opiate user, family members, friends, or domestic partners of the active opiate user for the purpose of ensuring greater community access and decreasing opiate overdose fatalities statewide. The New Mexico Board of Pharmacy (NMBOP) requires that a naloxone prescription specify:

- 1. The name of the individual to whom the medication is prescribed;
- 2. The name of the clinician with the authority to prescribe the medication;
- 3. An entry into the medical record that defines the prescribing event and the medical indications for the prescription.

The clinician authorized to prescribe naloxone will hereafter be referred to as the "prescribing clinician". Under an entity's OPTP protocol, individuals who staff an NMDOH-sanctioned OPTP may provide naloxone under the authority of the prescribing clinician. These individuals must be trained and certified by the NMDOH Harm Reduction Program to provide overdose education, as well as naloxone (if indicated) and use the training guidelines and best practices provided by NMDOH. Trained staff working within an NMDOH-sanctioned OPTP will hereafter be referred to as the "OPTP Staff".

Training of a participant for the use of naloxone includes:

- 1. A discussion of the indications, contraindications, potential adverse reactions, and administration of the medication.
- 2. A discussion of logistic considerations, such as storage in a relatively stable environment, avoiding direct sunlight or excessive freezing or heat, are discussed.
- Information regarding the expiration date of the medication and instruction to the participant to discard the prescribed medication and return for a new supply before the currently prescribed syringes expires, and not to use the drug if the solution is cloudy.

Following completion of the training, the trainer will complete a "Narcan Enrollment/Record of Use Form" that is sent to the Harm Reduction Program in Santa Fe. A chart will also be created in the entities records that includes (at least) the minimum elements of a medical record: the name and date of birth of the participant; participant allergies (or no known allergies); the medical indication for the prescription if naloxone; and documentation that the participant has completed overdose prevention training that is approved by the Harm Reduction Program, and been informed and understands the indications, contraindications, potential adverse reactions, and proper administration of the drug. The participant will receive a "Narcan Card."

#### 5. Naloxone Dispensing

The process for clients picking up naloxone includes:

- 1. The participant can present to an entity that maintains an OAAP and that provides naloxone and present their Narcan Card. If the client does not have a "Narcan Card," their unique identifier number can be obtained by calling the Harm Reduction Program in Santa Fe to confirm training if necessary. Note: this step has already been completed if the dispensing occurs immediately following participation in training.
- 2. The OPTP staff will complete the Narcan Enrollment/Record of Use Form and the appropriate clinic Medical records and call any clinician assigned to the clinic or program for a verbal order to dispense naloxone as outlined in the programs protocols.
- 3. The OPTP staff will document the phone order in the participant's medical record and on the Narcan Enrollment/Record of Use Form. Task the prescribing clinician to sign the order, if necessary.
- 4. The OPTP staff will dispense the naloxone using the entity's pharmacy sign-out procedure. Each box containing the naloxone must be labeled with a label indicating the name of the participant, the name of the prescribing clinician, the date and the instruction for the use of the medication.

#### References

None

#### **Attachments**

- Narcan Enrollment/Record of Use Form
- Enrollment Card (sample)

#### PUBLIC HEALTH DIVISION CLINICAL PROTOCOL/MANUAL APPROVAL SHEET

PROGRAM/BUREAU: Harm Reduction Program/Infectious Disease Bureau CLINICAL PROTOCOL/MANUAL TITLE: Overdose Prevention Training Protocol -External Programs Reviewed by: (Must have a signature from at least one clinical user of the Clinical Protocol.) User Reviews: Deminist Ve Burlo Name:\_{/ LINDA GURGOS Date: Name: Date: Name: Date: Name: Date: Name: Approved by: Program Manager<u>//</u> Date Bureau Chief **Date** 27/≱∌747 Bureau Medical Director PHD Medical Director Date RegionalHealth Office PHD Chief Nurse PHD PROTOCOL FOR DEVELOPMENT AND REVISION OF CUNICAL PROTOCOLS/8, Leapvill & B. Hiskok November 2011

#### NMDOH NORTHWEST PUBLIC HEALTH REGION

#### NALOXONE STANDING ORDERS

#### Introduction

Public Health Offices where Overdose Prevention Training Program (OPTP) services are provided should be able to dispense naloxone even if a clinician is not available. This standing order enables NMDOH nursing staff to dispense naloxone to OPTP clients. A client is an individual who is enrolled in the OPTP program, which includes formal training in naloxone use from an NMDOH Harm Reduction Program-approved trainer.

#### Order:

- 1. To document that the client is trained in naloxone use, the client must either possess an NMDOH "Narcan card" with their name on it or their name can be found in the files or data base used by the OPTP. Call the Harm Reduction Program Manager in Santa Fe to confirm training if necessary.
- 2. Using the BEHR Harm Reduction (HR)/Narcan template, update the record, including the Reason for Visit, HPI (History of Present Illness), PMH (Past Medical History), Family Hx (Family History), and Personal Hx (Personal History). This includes:
- If one or more doses of naloxone have been previously dispensed to the client, and, if so, the status of the medication (e.g., expired, lost, administered).
- If one or more doses have been administered by or to the client, document this in the BEHR note and complete a "Narcan Enrollment/Record of Use" form with the client for each use. These forms are mailed to the Harm Reduction Program in Santa Fe on a monthly basis.
- Document any problems with administration (e.g., allergic reaction, pulmonary edema).

If BEHR is not available (e.g., during an outreach) use the then use BEHR-down processes – see <a href="http://intranet/PHD/behr.html">http://intranet/PHD/behr.html</a> and <a href="http://intranet/PHD/clinicalForms.html">http://intranet/PHD/clinicalForms.html</a>. Record the encounter in BEHR as soon as possible - these forms may be destroyed once entry into BEHR has been completed.

- 3. If there are no new medical contraindications or prior problems with use of naloxone, and the client requests additional doses, dispense two (2) pre-filled syringes of naloxone (2mg in 2cc) for intranasal use and a Mucosal Atomization Device (MAD) using DOH pharmacy sign-out procedures (i.e., each box must be labeled with a NMDOH Pharmacy label indicating the name of the participant, the name of the prescribing clinician, the date, and the instruction for the use of the medication). Note that more doses may be provided depending on the conditions indicated by the participant, such as lengthy travel or limited hours of availability.
- 4. Provide a drug information sheet with the medication (http://intranet/PHD/PharmacyDIS.html).

PLEASE see the NMDOH Harm Reduction Protocol at <a href="http://intranet/PHD/clinical\_protocols.html">http://intranet/PHD/clinical\_protocols.html</a> for further recommendations and requirements regarding medication administration including enrollment procedures.

For any issues not covered by this order, please contact the Regional Health Officer or other designated prescribing clinician for further guidance.

Please place this standing order with your Harm Reduction AND your Standing Orders Notebook.

Prescribing Clinician Name: Ralph S. Hansen, MD, Regional Health Officer

Signature: Signature: Date: July 24, 2014

State of New Mexico

Department of Health

**Public Health** 

Central Pharmacy Warehouse





**APRIL 2013** 

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Cabinet Secretary, Department of Health Chief Medical Officer, Department of Health Division Director, Public Health Division Medical Director, Public Health Division Deputy Director, Public Health Division Chief Nurse, Public Health Division Pharmacy Program Manager

Director of Pharmacy Staff Pharmacist

#### **DRUG ROOM NURSES**

Metro Region

Alamosa Westside Metropolitan Detention Center

Midtown NE Heights NW Valley SE Heights SW Valley Belen Cuba Estancia

Los Lunas Moriarty

Sandoval Health Commons

Olivia Lopez-Barlow Cynthia Randolph Elizabeth Carbajal Heather Black Loretta Mendoza Linda Hellyer Shelly Ogle Melinda Ivey Karolyn Schaefer

Debra Chambers Paula Thomas Deborah Chambers Ester Acosta

**NERegion** 

Clayton Espanola Las Vegas Los Alamos Mora Raton

Santa Fe Santa Rosa Taos

**NW Region** 

Bloomfield Farmington Gallup Grants

SE Region

Artesia Carlsbad Clovis Dexter Ft. Sumner Hobbs Lovington Sybil Dykes Terry Waters Darlene Shelton Felicia Branch Darlene Shelton Sybil Dykes Veronica Trujillo Susan Oviedo Katherine Dick

Kathy Harris Kathy Harris Melissa Elkins Melissa Charlie

Angie Milligan Angie Milligan Teresa Broeker Kelly Bassett Nancy Giannini Diane Gaston Carrie White

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Portales Carol Morgan
Roswell Lisa McDonald
Ruidoso Martha Ordorica
Tucumcari Jacqueline Dominguez

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Chaparral Tina Bunton
Deming Dolores Coronado
Dona Ana Village, Las Cruces Deborah Hanus

Hatch Josefina Vanderwagen
Las Cruces Josefina Vanderwagen

Lordsburg Margaret Diaz
Silver City Margaret Diaz
Socorro Ruth Guin
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Truth or Consequences Serena Sanchez
West Las Cruces Barbara Marta

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# **MISSION STATEMENT**

The mission statement of the Public Health Division of the Department of Health is to work with individuals, families, and communities in New Mexico to achieve optimal health. We provide public health leadership by developing health policy, sharing expertise with the community, ensuring access to the coordinated systems of care, and delivering services to promote health and to prevent disease, injury, premature death, and disability.



# **SCOPE OF PRACTICE**

The scope of practice of the Department of Health, Public Health Division, Pharmacy and Local Public Health Office (LPHO) Drug Rooms is to provide drugs and services to the citizens of New Mexico. LPHO Drug Rooms may dispense drugs which treat a variety of life and non-life threatening diseases. Vaccines may be administered to all children and some adults who may present to the LPHO. The following programs are included in Public Health:

<b>Chronic Disease Bureau</b>
Diabetes Prevention and
Control
Arthritis and Worksite
Health
Tobacco Use Prevention
and Control
Cancer Programs: Breast
and Cervical,
Comprehensive,

Colorectal

Family Health Bureau
Family Planning
WIC
Children's Medical
Services
Maternal Health
MCH Epidemiology
Child Health
Families FIRST

# Infectious Disease Bureau STD Immunization Tuberculosis Refugee Health HIV/AIDS Prevention HIV/AIDS Treatment Medical Cannabis Hepatitis/Harm Reduction

Health Systems Bureau
Office of Adolescent and
School Health
Office of Oral Health
Office of Primary Care and
Rural Health
Office of Health Promotion
and Community Health
Improvement
Office of Community Health
Workers

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# SECTION I PURPOSE AND DEFINITIONS

### A. Purpose

- 1. To establish policies and procedures governing all pharmacy functions in the Public Health Division (PHD) and the Local Public Health Office (LPHO).
- To comply with state and federal laws and regulations relating to the procurement, storage, labeling, security, repackaging, dispensing, and record keeping requirements for dangerous drugs.
- 3. To assure quality pharmaceutical services consistent with attaining high standards of patient care for all recipients of LPHO services.
- 4. To provide a written agreement between the PHD Pharmacists and the Public Health Division for the Pharmacists to act as Consultant Pharmacist to the LPHO.

#### B. Definitions

- 1. <u>Administer</u> means to give a unit dose of medication to a patient as a result of an order of a licensed clinician.
- 2. <u>Authorized Personnel</u> The designated drug room nurse and any provider given access by the drug room nurse. Access will be limited to licensed providers. For offices with a large number of staff, the drug room nurse may issue a key to the drug room to be shared by on duty staff during the day and returned to the drug room nurse in charge at end of day.
- 3. NMBOP means the New Mexico Board of Pharmacy.
- 4. <u>Central Pharmacy, Pharmacy or Pharmacy Warehouse</u>— means the Public Health Division's pharmacy and warehouse that provides for the safe storage, preservation and control of dangerous drugs that are shipped to the LPHOs of the Department of Health; and where dangerous drugs are repackaged from bulk containers into dispensing units or where drug units are re-labeled for dispensing by the LPHOs.
- 5. <u>Consultant Pharmacist</u> means a Registered Pharmacist holding a current active license, issued by the New Mexico Board of Pharmacy. The PHD pharmacists or a contracted pharmacist will provide the consultant services as required by the NMBOP to:
  - a. Assist in drawing up correct procedures, rules and regulations for the distribution of dangerous drugs;
  - b. Assume the overall responsibility for the system of control and distribution of dangerous drugs;
  - c. Ensure that a designated person has the responsibility of day to day operations of the drug room;
  - d. Visit the LPHO on a scheduled basis dictated in NMBOP laws in the course of their duties; and,
  - e. Conduct chart audits centrally in Santa Fe via a secure FTP server.
- 6. <u>Dangerous Drug</u> means a drug that is determined by law to be unsafe for self-medication this is enumerated in the New Mexico Drug, Device and Cosmetic Act (Chapter 26, Article 1, NMSA 1978) and in FDA laws and regulations.
- 7. <u>Dispense</u> means to issue to a patient or a person on their behalf, one or more unit doses of medication which may result from compounding or from repackaging from a bulk or original container.
- 8. <u>Dispensing Label</u> means when a drug is prescribed by the licensed prescriber, the following information shall be affixed to the dispensing unit:
  - a. Name of patient.
  - b. Name of licensed prescriber.
  - c. Name and strength of drug.
  - d. Directions for use.
  - e. Name, address, and telephone number of the LPHO
  - f. Prescription number, if applicable.
  - g. Date dispensed.
  - h. Initials of person dispensing.
- 9. <u>Dispensing Unit</u> means a container or containers of a drug, either re-labeled in the manufacture's original container, or repackaged by the Central Pharmacy containing a quantity suitable for the prescribed treatment or condition.
- 10. Distribute means delivery of a dispensing unit by a licensed provider to a patient of the

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- LPHO by means other than dispensing.
- 11. Regional Health Officer (RHO) means the physician employed by the Department of Health/Public Health Division who is responsible for clinical services, including prescribing dangerous drugs, within the region.
- 12. <u>Drug Room</u> means the designated secure area of the LPHO which provides the proper and safe storage, preservation and control of drugs, vaccines and medical supplies. Refrigerators and freezers used to store drugs or vaccines are to be considered auxiliary drug rooms and must be secure.
- 13. <u>Drug Room Nurse</u> means the designated licensed nurse in charge of the proper maintenance of the LPHO drug room.
- Formulary means a list of drugs approved for administration or for dispensing in the LPHO by the medical staff and approved through the Pharmacy and Therapeutics Committee or its equivalent.
- 15. <u>Medication Profile</u> means a record and drug listing for each patient based on available information, containing but not limited to, patient name, patient age, sex, patient weight, current diagnosis, allergies or sensitivities, and current therapy.
- 16. <u>Local Public Health Office (LPHO)</u> means a NMBOP licensed facility where one or more licensed providers diagnose and treat patients, and where dangerous drugs are:
  - a. Stored in a drug room for use in the LPHO;
  - b. Administered to patients of the LPHO;
  - c. Dispensed to patients of the LPHO;
  - d. Repackaged from bulk containers to dispensing units on the premise for dispensing to patients of the LPHO in compliance with the NMBOP regulations;
  - e. Limited to procurement and storage of the drugs listed in the Formulary.
- 17. Orphaned means there is no program overseeing a condition.
- 18. <u>Patient Counseling</u> means communication with a patient or his agent regarding dispensing of a prescription drug or drugs.
- Pharmacy and Therapeutics Committee means an advisory committee of the medical staff of the department recommending policy regarding evaluation, selection, and therapeutics of drugs.
- Pharmacy Audit means a chart audit of 5% of dispensed drug/s to assure compliance with the New Mexico Board of Pharmacy regulations and to set a PHD standard for provision of quality services to clients receiving medications through PHD programs as outlined in Section IV.D.1.
- 21. <u>Physician</u> means a person licensed as an MD or DO by any state, territory or possession of the United States who, within the limits of their license, may lawfully prescribe, dispense or administer drugs for the treatment of a patient's condition.
- 22. <u>Prescriber</u> a person whose license permits them to prescribe dangerous drugs. This includes physicians, physician assistants and nurse practitioners.
- 23. <u>Prescription</u> means an order given individually, or by written standing order for the patient(s) for whom prescribed, either directly from a licensed prescriber to the pharmacist or indirectly by means of a written order signed by the prescriber.
- 24. <u>Provider</u> A licensed individual. This includes nurses, nurse practitioners, physician assistants and physicians.
- 25. <u>Procedure Manual</u> means a manual that the Consultant Pharmacist shall set forth the procedure outlining the system of control and accountability of drug distribution in the LPHO; and listing the drugs that may be procured for use and their method of procurement and secure storage.
- 26. <u>Secure Area</u> means that area designated to properly store dangerous drugs and which is to remain locked in the absence of the Drug Room Nurse. Refrigerators and freezers are considered to be a secure area.
- 27. <u>Standing Order</u> means a medical order written by a physician, usually the RHO, which authorizes program protocols that direct patient care or treatment. Also to include medical orders directing an immediate or special change in care or treatment of an "orphaned" condition.

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# SECTION II LOCAL PUBLIC HEALTH OFFICE DRUG POLICY AND PROCEDURE

- A. Licenses and Permits
  - 1. Each LPHO shall display the following:
    - a. The current New Mexico Board of Pharmacy Clinic license;
    - b. The most recent New Mexico Board of Pharmacy Inspection Report;
    - c. The current copy of the Consultant Pharmacist's license;
    - d. The most recent copy of the Consultant Pharmacist's Inspection Report;
    - The current copies of certificate of registration of all licensed medical personnel of the LPHO.
  - 2. Copies of all licenses shall be marked "COPY" or "VOID" and displayed in a secure manner.
- B. Reference Material
  - 1. Reference material in each LPHO shall include, but not limited to the following:
    - a. The Pharmacy Procedures Manual for Public Health Division LPHO:
    - b. The current dispensing and administration formulary;
    - c. The New Mexico Board of Pharmacy Laws and Regulations via the web;
    - d. A current subscription to Clinical Pharmacology via the web;
    - e. The telephone number for the New Mexico Poison Center: 1-800-222-1222
    - f. Education Line 1-877-432-0002
- C. Authorized Personnel
  - 1. The Drug Room Nurse and the RHO, under procedures established by the Consultant Pharmacist, shall supervise the drug room.
  - 2. The drug room shall be accessible only to authorized personnel and kept locked when such person(s) are not physically present in the drug room. A designated spare key may be kept in the facility when the Drug Room Nurse is not present and used only by authorized personnel. Master keys or keyed-alike locks are not allowed: the drug room key shall not open any other door. Drug Inspectors from the NMBOP are <u>not</u> authorized personnel and are permitted in the Drug Room only when accompanied by authorized personnel of the LPHO. An alternative to a key lock shall be a combination lock whose combination is restricted only to authorized personnel.
  - 3. The Drug Room Nurse is the designated licensed nurse in charge of the proper maintenance of the drug room and is responsible for:
    - a. Maintenance of drugs and drug inventories.
    - b. Order and receipt of drug and medical supplies.
    - c. Proper storage of drugs.
    - d. Proper control of drugs as outlined in this manual.
    - e. Drug room, refrigerator and freezer security.
    - f. Cleanliness.
    - g. Notifying the central pharmacy of all changes in Drug Room Nurse personnel.
    - h. Notifying the central pharmacy, at least 10 days in advance, of all closures of the facility.
  - 4. In the event the Drug Room Nurse and other authorized persons are not present in the LPHO, access to the drug room is strictly prohibited.
- D. Drug Room Maintenance
  - 1. There shall be the required space, as defined by the NMBOP Regulations, for the proper storage of drugs. The drug room shall be at a satisfactory location within the LPHO that provides for proper ventilation, lighting, temperature control and refrigeration. The Consultant Pharmacist shall determine the proper space requirements as outlined in the NMBOP Regulations.
  - 2. A maximum/minimum type thermometer shall be utilized for adequate temperature control. Room temperature shall be maintained between 68°F to 78°F (20°C to 25°C) for all rooms where drugs and/or laboratory supplies are kept. Freezer temperature shall be maintained at ≤32°F (≤0°C). Varicella freezer temperature shall be maintained at ≤5°F (≤-15°C). Refrigerator temperature shall be maintained between 35°F to 46°F (2°C to 8°C). A drug room temperature log is to be kept for all rooms with drugs and or laboratory supplies. The room temperature, minimum and maximum readings are to be recorded once daily before being reset. Temperature readings outside the proper range should be reported to the pharmacy or the Vaccines for Children (VFC) program as soon as possible after it is recognized.

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- 3. Dangerous drugs must be stored in an appropriately secured space to limit access when authorized personnel are not in attendance. The space shall be locked at all times.
- 4. All drug containers in the drug room and LPHO shall be clearly and legibly labeled as required by law. Any container not properly labeled is to be returned to the central pharmacy.
- Purchase, storage and control of dangerous drugs shall be such as to prevent outdated, deteriorated, impure or improperly standardized drugs in the LPHO.
- 6. Returns are to be stored in a separate secure area until returned to the central pharmacy.
- 7. Access to the drug storage area shall be limited to authorized personnel or others designated by the Consultant Pharmacist.
- 8. Copies of the NMBOP of Pharmacy Inspections shall be forwarded to the central pharmacy immediately after the inspection is completed.
- E. Emergency Tray Drugs
  - 1. All emergency tray drugs will be inspected regularly to avoid outdated, deteriorated or improperly stored drugs in the tray.
  - 2. The basic standard emergency tray shall contain the following items:

ItemQuantityEpinephrine 1:1000 1ml5 ampsDiphenhydramine Inj. 50mg/ml 1ml3 ampsOxygen Equipment1 Unit

3. Refer to PHD Emergency Medical Response Protocol found on the PHD intranet (<a href="http://intranet/PHD/documents/PHDEmergencyMedicalResponseProtocolJanuary2012FINAL.doc">http://intranet/PHD/documents/PHDEmergencyMedicalResponseProtocolJanuary2012FINAL.doc</a>) for additional emergency tray items and procedures.

## F. Injectable Drugs

- 1. The LPHO shall use single dose vials for parenteral additives or medications when possible
- 2. Multi Dose Vial (MDV) use shall be limited to a centralized area in the LPHO. (For vaccines in MDV, see section F.4.)
  - a. Aseptic technique shall be used when using a MDV.
  - b. After initial entry or use of a MDV the vial shall be dated and stored per guidelines in the manufacture's package insert for a maximum of 28 days or the expiration dating on the product whichever is less. Expiration dating not specifically referenced in the package insert shall not exceed 28 days.
  - c. Discard the MDV if there is any reason to suspect loss of sterility such as visual signs of contamination or loss of integrity of the MDV.
- 3. Reconstituted Drugs
  - a. Reconstitute the drug per the package insert guidelines.
  - b. Dispose any unused drug if it is not to be stored.
  - c. If the drug is to be stored, date the vial, assign an expiration date to the vial, and store the vial per manufacture guidelines.
  - d. Discard the drug if there is any reason to suspect loss of sterility or if improperly stored.
- 4. Vaccines
  - a. All vaccines in the LPHO will follow the storage and use guidelines of the CDC.
  - b. Storage and use guidelines can be found on line via the web at: www.cdc.gov/vaccines/pubs/downloads/bk-vac-mgt.pdf
- G. Drug Carts
  - 1. Public Health offices that utilize a drug cart or medication cart will assure that:
    - a. The cart is locked when not being accessed.
    - c. Dispensing logs are in place for each drug on the cart.
    - d. The cart is monitored for room temperature storage ranges and a log is kept to document proper storage, 68° to 77°F, or the room is monitored with a log.
    - e. The cart is stored in the drug room overnight and when not in use.

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#### SECTION III PROCUREMENT AND RECEIPT OF DANGEROUS DRUGS

- A. Records Required
  - 1. The LPHO shall have proper records for the receipt and disposition of dangerous drugs.
    - a. Receipt Records
      - i. All dangerous drugs received by the LPHO shall have an invoice originated by the provider and shall be preserved for 3 years.
      - ii. All dangerous drugs returned to the central pharmacy shall have the required forms properly completed and enclosed with the return. One copy shall be kept on file in the LPHO for 3 years.
      - iii. Emergency transfers between LPHO of dangerous drugs shall be recorded on Dangerous Drug Sign Out Sheet and a completed Drug Item Transfer Report shall accompany the transfer. The original shall be kept in the providing LPHO and a copy shall be forwarded to the central pharmacy. Vaccines may be transferred on forms provided by the Immunization Program and a copy sent to the VFC program. All copies shall be kept on file in the LPHO for 3 years.
      - iv. There should be no routine transfer of dangerous drugs, vaccines or medical supplies.
- B. Controlled Drug Policy
  - 1. Controlled substances shall not be stored or dispensed in the LPHO.
- C. Sample and Donated Drug Policy
  - 1. Sample and donated drugs shall not be stored or dispensed in the LPHO.
- D. Ordering Procedure
  - 1. Drug procurement and storage is limited to the drugs listed in the dispensing and administration formularies for the LPHO.
  - 2. All requests for drugs and medical supplies shall be submitted to the central pharmacy.
    - a. Routine monthly drug and medical supply orders shall be transmitted by email using the pharmacy excel work book. All orders and correspondence are to be sent to the email group "doh-pharmacy orders". Each LPHO should order once a month following this schedule: Metro Region and NW Region week four, except for the Midtown Public Health Office that orders week two and week four, NE Region week three, SE Region week two, and SW Region week one of each month, except for the Las Cruces LPHO that orders week one and week three.
    - b. Special and emergency orders may be made at any time by email.
  - Shipments, which must be maintained at a low, reduced or frozen temperature, shall be shipped on Monday through Thursday of the week unless the LPHO is closed or on holidays, and must be scheduled to arrive when authorized personnel are available to receive and store the shipment.
  - 4. Drugs not on the Formulary may be requested through the central pharmacy on a patient-specific basis.
  - 5. An adequate drug supply not to exceed a <u>TWO</u>-month supply should be kept in the LPHO drug room inventory. Excess in date items or items not being used should be returned immediately to the central pharmacy. A return authorization should be obtained from the pharmacy warehouse manager at which time a return shipping label may be requested for the package.
  - 6. Upon receipt of drugs, the Drug Room Nurse shall ascertain that the drugs were received correctly as ordered. The central pharmacy shall be notified immediately upon the receipt of any questionable drugs, damaged items, shortages, errors, etc.
  - 7. Styrofoam containers that have cooler or freeze packs should be opened <u>IMMEDIATELY</u> and the contents placed in the proper storage area. GelPacks or freeze packs, including the styrofoam container, should be returned to the central pharmacy using the ARS label from UPS. **DO NOT INCLUDE ANY OTHER ITEMS IN THE CONTAINER.** Styrofoam, coolers or freeze packs must not be stored outside. Return only clean, dry and undamaged containers.
  - 8. Orders not received on the electronic order form will not be processed. Use the Electronic Pharmacy Order Form for all orders. The latest form can be located on the PHD Intranet, under the Pharmacy tab.
  - 9. Drugs should be grouped according to refrigerated and non-refrigerated items. Refrigerated items should be located at the top of the form.
  - 10. Vaccines are required to be ordered from the VFC program directly.

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#### E. Out of Stock

- 1. Any item out of stock will be marked back order.
- 2. Back orders will be filled when inventory is received in the warehouse.
- 3. Partial orders will be considered complete.
- 4. If the LPHO is out of an item and cannot wait for the back order the drug room nurse can call the warehouse or another LPHO for the stock.

# SECTION IV DISTRIBUTION, DISTRIBUTION RECORDS and ADMINISTRATION

# A. Distribution Procedure

- It is <u>UNLAWFUL</u> for any person other than a pharmacist or physician to count out medication into a container and/or attach a label to the container. All drugs must be stored in the dispensing units packaged by the central pharmacy, or in the original manufacturer container.
- 2. The central pharmacy warehouse will prepare all dispensing units with a prescription label. Any unit prepared by a physician shall bear a prescription label with the following information:
  - a. Name, strength and quantity of drug.
  - b. Lot number or control number.
  - c. Name of manufacturer.
  - d. Expiration date.
  - e. Date drug was repackaged.
  - f. Initials of re-packager.
  - g. Federal caution statement.
  - h. Name of patient.
  - i. Name of prescriber.
  - Date of dispensing.
  - k. Name, address, and phone number of the LPHO.
  - . Prescription number, if applicable.
- Drugs shall be dispensed or distributed only to LPHO patients on the order of a licensed prescriber of the LPHO or under an approved PHD protocol or standing order. This includes all prescription and over the counter drugs.
- 4. All drugs dispensed will be documented in the patient's medical record at the LPHO.
- 5. The following procedure shall be followed:
  - a. After the licensed prescriber determines the appropriate drug therapy through a direct written order or written standing order, the information shall be recorded on the patient's medical chart indicating the name and dosage of the drug and the length of time (or quantity) the drug is to be used by the patient. The prescriber shall sign the medical record.
  - b. The dispensing unit container shall bear a prescription label with the information as required by law.
  - c. The Drug Room Nurse shall read the drug order, select the correct drug dispensing unit and complete the dispensing label to include the LPHO name and address, telephone number, patient name, prescriber name, date the drug was delivered to the patient, directions for use and the initials of the nurse dispensing the drug.
  - d. The Drug Room Nurse or authorized personnel may dispense the full quantity or a partial quantity of the prescribed medication on the patient's intital clinic visit. The balance may be dispensed on subsequent patient visits after verification that the patient has an active order for the medication.
  - e. Upon dispensing the drug, the Drug Room Nurse or prescriber must counsel the patient with the following information: (additional counseling may be obtained from the Department Consultant Pharmacist at 1-800-254-4689)
    - i. The name and description of the drug.
    - ii. The dosage form, dose, route of administration and duration of drug therapy.
    - iii. Intended use of the drug and expected action.
    - iv. Special directions and precautions for preparation, administration and use by the patient.
    - v. Common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.

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- vi. Techniques for self-monitoring drug therapy.
- vii. Proper storage.
- viii. Actions to be taken in the event of a missed dose.
- ix. A drug/patient monograph shall be given to the patient for each drug dispensed and will include information on the following:
  - 1. Drug name and description.
  - 2. Use.
  - 3. How to use.
  - Side effects.
  - 5. Precautions.
  - 6. Missed dose.
  - 7. Storage.
  - 8. Consultant Pharmacist telephone number 1-800-254-4689. Hours available for counseling shall be 7:30am through 5:00pm Monday through Friday.

#### 6. Inter-LPHO Distribution

- a. All drugs and medical supplies shall be distributed from the central pharmacy.
- b. Each LPHO may, on an as needed basis, transfer inventory from one LPHO to another LPHO in order to balance stock and prevent a temporary loss due to storage conditions or limit loss due to expiration dating. A copy of all transfer reports shall be sent to the central pharmacy.
- c. See Transport and Deliver Protocol for guidelines.

#### B. Distribution Records

A record shall be kept of dangerous drugs dispensed indicating the date the drug was dispensed, name and address of the patient, the name of the licensed prescriber, and the quantity and strength of the drug dispensed. The individual recording the information shall initial the entry.

- 1. This record shall be maintained separate from the individual patient medical record and shall be open to inspection by a law enforcement officer of the NMBOP.
- 2. The Dangerous Drug Sign Out sheet will be used for this purpose.
- 3. This dispensing record shall be kept for three years.

#### C. Administration

All dangerous drugs and medical devices are to be administered and utilized per nursing policy and procedure per program protocols. Any incident involving a drug or medical device is to be documented on the "Public Health Division Incident Report" form per nursing policy and procedure. A copy of each incident report is to be sent to the Pharmacy Warehouse for pharmacy review, per Regional procedures. The pharmacy will complete the FDA "MedWatch" report form if necessary.

It is the policy of the Public Health Division not to store nor administer non-formulary drugs.

1. Vaccines under the VFC program are excluded.

#### D. Patient Chart Audits

- 1. NMAC 19.4.11(2).A.8 requires each LPHO to complete the PHD Pharmacy Quality Assurance Audit Tool to be completed for not less than 5% of the LPHO's patients who have been dispensed dangerous drugs.
- 2. The form may be submitted daily, weekly or monthly via FileZilla.
- 3. The form must be filled out as completely as possible.
- 4. Prescriptions drugs dispensed, current prescriptions being taken, over the counter drugs by name, including alternative and herbal medications being taken are to be included in the appropriate spaces.
- 5. The excel file audit tool shall be used for this purpose.
- A PHD Pharmacist shall review and complete the tool and provide appropriate remarks or action plans as required. The form will be returned to the submitting LPHO in a timely manner.
- 7. Medication Interactions:
  - a. Level 1 (severe) interactions should be addressed immediately with actions taken and re-submitted to the Consultant Pharmacist for additional review. Level 1 interactions are defined as follows: The use of these medications together is contraindicated or the medications are not usually taken concurrently because the interaction may be life threatening or may cause serious harm. Avoidance of the drug

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- combination is preferred because of the risk: benefit ratio. Refer to the drug interactions comments for rare situations that might be an exception.
- b. Level 2 (major) interactions should be reviewed immediately. Level 2 interactions are defined as follows: These medications may result in the potential deterioration of the patient's condition from either an increase or decrease in the effect of at least one drug. The patient may need further therapy and/or an alternation in therapy to avoid or limit the potential for interaction. Alternative drug therapy may be preferred in selected cases. The patient should be monitored for the possible manifestations of the interaction. Refer to the drug interactions comments for rare situations that might be an exception.
- c. Level 3 (moderate) should be noted for future reference. Level 3 interactions are defined as follows: The interaction may be bothersome or unnoticeable with limited clinical effects. Manifestations of the interaction may consist of an increase in the frequency or severity of side effects or decreased effectiveness of a drug but normally would not require a major alteration in therapy. Depending on the clinical situation, the interaction risk may be minimized with selected actions. The patient should be monitored for the possible effects of this interaction. Refer to the drug interactions comments for situations that might be an exception.
- d. Level 4 (minor) should be noted for future reference. Level 4 interactions are defined as follows: The interaction may be bothersome or unnoticeable with limited clinical effects. Manifestations of the interaction may consist of an increase in the frequency or severity of side effects, or a decrease in the effect of the drug. However, the interaction normally would not require a major alteration in therapy or special precautions. The patient should be monitored for the possible effects of the interaction.
- 8. The original audit and all copies shall be retained for 3 years and open for inspection by a representative of the New Mexico Board of Pharmacy.

# SECTION V <u>DISPOSITION OF UNWANTED OR OUTDATED DRUGS</u>

- A. Unwanted or Outdated Drugs
  - 1. The Drug Room Nurse shall maintain the stock of drugs in such a manner as to remove all recalled, outdated, discontinued, or unusable drugs from the inventory.
  - 2. All damaged drugs, open dispensing units, or questionable drugs are to be returned to the central pharmacy. All packages must be returned by certified mail or UPS, signature required, as per New Mexico Board of Pharmacy Regulations.
  - 3. All drugs returned to the central pharmacy are to be listed on the proper form and marked as returned drugs. The reason for return must be stated on the form. A verified copy will be returned to the LPHO for filing.
  - 4. Drugs to be returned must be securely stored separate from the drug room inventory pending return to the central pharmacy.
  - 5. Overstock or drugs no longer being used may be returned to the central pharmacy as soon as possible before the expiration date. Authorization is required.
  - 6. Outdated drugs may also be returned by the PHD pharmacist during a LPHO inspection.
  - 7. Outdated, damaged, or unusable vaccines are required to be returned to the VFC contractor per VFC Program instructions. Contact the VFC program with questions.
- B. Returned Drugs by a Patient
  - Any drug returned to the LPHO by a patient must be returned to the central warehouse for destruction.
  - 2. The drug package shall be placed with drugs for return and so identified "Returned by Patient"
  - 3. Return of non-dispensed LPHO drugs is not permitted.
  - Under no circumstances may controlled substances be accepted for destruction by the LPHO.

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# SECTION VI LOCAL PUBLIC HEALTH OFFICE INVENTORY

#### A. Inventory

- Through the distribution record, a perpetual inventory is maintained using the Dangerous Drug Sign Out Sheet. The distribution record for each drug shall have the amount stated on hand (balance). The balance on the Dangerous Drug Sign Out Sheet shall correspond with the shelf inventory at all times.
- 2. A physical inventory is required to be taken as often as deemed necessary by the drug room nurse to account for inventory.

# B. Loss of Drugs

Any loss of drugs, vaccines, biological or medical supplies either by theft, damage, improper refrigeration or other cause is to be reported immediately to the Consultant Pharmacist. This report is to be made by telephone as soon as the loss is discovered and a written report is to follow. An "Investigation of Loss/Overage" report must be properly filled out and forwarded to the central pharmacy within 3 days. An inventory of items lost shall accompany the report.

## SECTION VII CONSULTANT PHARMACIST

- A. The Consultant Pharmacist shall provide in-service training to the LPHO staff on side effects, adverse reactions, contraindications and toxicity of drugs when requested, or as applicable.
- B. Repackaging
  - The pharmacy warehouse shall repackage and label all dangerous drugs from bulk containers to dispensing units as needed. The pharmacy warehouse will re-label all unit dose containers of dangerous drugs per FDA rules and regulations.
  - 2. Repackaging may take place by a pharmacist or physician in the LPHO per NMBOP laws and regulations, and as outlined above (IV.A.2).
- C. Duties and Responsibilities
  - 1. The duties and responsibilities of the Consultant Pharmacist are:
    - a. To comply with the federal and state laws and regulations relating to procurement, storage, labeling, security, repackaging, dispensing and record keeping requirements for dangerous drugs.
    - b. To ensure that drugs are handled in the facilities in a manner that protects the safety and welfare of the patient.
    - c. To set the policies and procedures in the facilities as related to all facets of drug handling and distribution; these policies and procedures are to be reviewed on an annual basis.
    - d. To visit the facility, commensurate with his duties, bi-annually as specified by the New Mexico Board of Pharmacy. A visitation log recording all visits shall be maintained by the LPHO.
  - 2. Miscellaneous
    - a. Reserved
- D. Agreements
  - Reserved

# SECTION VIII FORMS

SEE ELECTRONIC WORK BOOK AND PHD INTRANET PAGE

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# POLICY AND PROCEDURE SIGNATURE PAGE

This Policy and Procedures manual has been reviewed by the following administrative staff. The P&P manual is to be reviewed at least yearly.

George Gonzales, RPh Director of Pharmacy	Date
Maggi Gallaher, MD, MPH Medical Director, Public Health Division PHD	 Date
Eugene Marciniak, MD Regional Health Officer, SW Region	
Chris Novak, MD, MPH Regional Health Officer, NE Region	 Date
Keith Levitt, MD Regional Health Officer, SE Region	
Maggi Gallaher, MD, MPH Regional Health Officer, NW Region	- Date
Maggi Gallaher, MD, MPH Regional Health Officer, Metro Region	 Date

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# SECTION IX STAFF SIGNATURE PAGE

All staff who access the medication drug room and/or are involved in administration or dispensing of drugs must read and sign this Policy and Procedure manual. Please date, print, sign and initial below.

DATE	PRINT NAME	SIGNATURE	INITIALS

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# SECTION IX STAFF SIGNATURE PAGE (continued)

All staff who access the medication drug room and/or are involved in administration or dispensing of drugs must read and sign this Policy and Procedure manual. Please date, print, sign and initial below.

DATE	PRINT NAME	SIGNATURE	INITIALS
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# SECTION X REVISIONS

DATE	SECTION	PAGE	REVISION
4/3/2013	IX	16	Added section for a signature page for all staff accessing or administering drugs.
4/3/2013	Х	17	Added a revision page to track changes.
8/6/2013	I.B	7	Added language to define authorized personnel to licensed practioners
8/6/2013	II.G	10	Added drug cart language.
8/6/2013	IV.A.3	12	Added language to clarify prescription and over the counter drugs.
8/6/2013	IV.C	13	Deleted language to allow for storing and administering non-formulary drugs.
8/6/2013	V.B.3	14	Clarified language to prohibit accepting non-dispensed drugs for destruction.
8/6/2013	IX	18	Added second signature page for large offices.

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#### NMAC 20.9.8.13

# INFECTIOUS WASTE.

- A. This section applies:
- (1) without regard to the quantity of infectious waste generated, to any generator of infectious waste including, but not limited to:
  - (a) general acute care hospitals;
  - (b) skilled nursing facility or convalescent hospitals;
  - (c) intermediate care facilities;
  - (d) in-patient care facilities for the developmentally disabled;
  - (e) dialysis clinics;
  - (f) free clinics;
  - (g) community clinics;
  - (h) employee clinics;
  - (i) health maintenance organizations;
  - (i) home health agencies;
  - (k) surgical clinics;
  - (l) urgent care clinics;
  - (m) acute psychiatric hospitals;
  - (n) blood/plasma centers;
  - (o) laboratories;
  - (p) medical buildings;
  - (q) physicians offices;
  - (r) veterinarians;
  - (s) dental offices;
  - (t) acupuncturists;
  - (u) funeral homes;
  - (v) eye clinics; and
  - (w) tattoo parlors and body-piercing establishments; and
- (2) to all infectious waste storage areas, processing, transformation, transfer and disposal facilities, other than sewage treatment systems that provide secondary treatment of waste.
- B. All material that has been rendered non-infectious is not subject to the handling requirements of this section, provided:
- (1) if it is an otherwise regulated, hazardous, special, or radioactive waste, it shall be handled according to regulations applicable to that type of waste;
- (2) any person that processes or transforms infectious waste shall certify in writing on at least an annual basis, or upon any change that could affect the efficacy of the treatment that the waste has been rendered non-infectious by sterilization, incineration or another method approved by the secretary; a certification that the waste has been rendered non-infectious shall be provided to the generator, transporter, and disposal facility; the generator, processing or transformation facility, and disposal facility shall maintain copies of certifications for a period of three years and the records shall be made available to the department upon request; and
- (3) the operator of the disposal facility applies daily cover as required in 20.9.5.9 NMAC prior to any compaction of the sharps.
  - C. The following storage and containment requirements apply to all infectious waste.
- (1) Containment shall be in a manner and location which affords protection from animal intrusion, does not provide a breeding place or a food source for insects and rodents, and minimizes exposure to the public.
- (2) Infectious waste shall be segregated by separate containment from other waste at the point of origin.
- (3) Except for sharps, infectious waste shall be contained in plastic bags inside rigid containers. The bags shall meet the testing requirements specified by 40 CFR 173.197. All bags used for containment purposes shall be red or orange and clearly identified as specified in 29 CFR 1910.145(f). The bags shall be securely tied to prevent leakage or expulsion of solid or liquid wastes during storage, handling or transport.
- (4) Sharps shall be contained for storage, transportation, transfer, processing, transformation, and disposal in leak-proof, rigid, puncture-resistant containers which are manufactured for the purpose of sharps containment and are taped closed or tightly lidded to preclude loss of contents.

- (5) Rigid containers shall be labeled "biomedical waste", or otherwise conspicuously labeled as holding infectious waste, or placed in disposable bags used for other infectious waste. Rigid containers shall meet or exceed the requirements of 49 CFR 173.197 including that the containers be:
  - (a) rigid;
  - (b) leak resistant;
  - (c) impervious to moisture;
  - (d) of sufficient strength to prevent tearing or bursting under normal conditions of use;
  - (e) sealed to prevent leakage during transport; and
  - (f) puncture resistant for sharps and sharps with residual fluids.
- (6) If other waste is placed in the same container as regulated infectious waste, then the generator shall package, label and mark the container and its entire contents as infectious waste.
- (7) Rigid infectious waste containers may be reused for infectious or non-infectious waste if they are thoroughly washed and decontaminated each time they are emptied or the surfaces of the containers have been completely protected from contamination by disposable, unpunctured or undamaged liners, bags, or other devices that are removed with the infectious waste, and the surface of the containers have not been damaged or punctured.
- (8) Storage and containment areas shall protect infectious waste from the elements, be ventilated to the outdoors (unless refrigerated), provide refrigeration as necessary, be only accessible to authorized persons, and be marked with prominent warning signs on, or adjacent to, the exterior doors or gates. The warning signs shall be easily read during daylight from a distance of 25 feet.
- (9) Generators of infectious waste, shall place sufficient absorbent material inside the rigid container or liner of the rigid container sufficient to absorb the entire amount of liquid present in the event of an unintentional release of contents, as specified in 49 CFR 173.197.
- (10) Compactors, grinders or similar devices shall not be used to reduce the volume of infectious waste before the waste has been rendered non-infectious unless prior approval has been obtained from the department.
- D. All generators of infectious waste shall dispose of the infectious waste at a facility permitted to process, store or dispose of infectious waste.
- E. All infectious waste generation, processing, transformation, transfer, storage and disposal facilities subject to this section shall comply with the following operational requirements.
- (1) Every person who generates, transports, stores, processes, or disposes of infectious waste shall prepare and maintain on file a management plan for the waste that identifies the type of waste the person generates or handles, the segregation, packaging, labeling, collection, storage, method of storage, and transportation procedures to be implemented, the processing, transformation or disposal methods that will be used, the transporter and disposal facility that will be used, and the person responsible for the management of the infectious waste.
- (2) All infectious waste management facilities may only accept infectious waste that is accompanied by a manifest that contains the information required by 20.9.8.19 NMAC.
- (3) Report to the secretary any delivery of unauthorized waste, contamination of any person, or other emergencies immediately upon recognition.
- (4) Human fetal remains, as defined by the state medical investigator, when measured to be 500 grams or greater, shall be disposed by incineration or interment.
- (5) Infectious waste consisting of recognizable human anatomical remains shall be disposed by incineration or interment, unless such remains are subject to different treatment or disposal standards due to contamination by a hazardous or radioactive substance. Recognizable human anatomical remains may be released to the patient, proper governmental authority, or designated family member for interment or incineration, as long as all forensic needs of the facility have been met and the release is not in violation of any other law.
- F. Processing, transformation and disposal of infectious waste shall be by one of the following methods:
- (1) incineration in a controlled air multi-chambered incinerator which provides complete combustion of the waste to carbonized or mineralized ash:
- (a) ash from the incinerator shall be sampled in accordance with Subsection B of 20.9.8.11 NMAC;
- (b) the sample shall be analyzed by the U.S. EPA test method 1311: toxic characteristics leaching procedure (TCLP) to determine if it is a hazardous waste; if hazardous, it shall be managed by applicable state regulations;

- (c) the retention times and temperatures for each chamber shall be continuously measured and recorded, or other equivalent tests approved by the department to determine if it is still infectious shall be performed; if infectious, it shall be reincinerated in accordance with this section; and
  - (d) charge rates shall be maintained and recorded;
  - (2) sterilization by heating in a steam sterilizer so as to render the waste non-infectious:
- (a) the operator shall have available and shall certify in writing that she or he understands written operating procedures for each steam sterilizer including time, temperature, pressure, type of waste, type of container(s), closure on container(s), pattern of loading, water content, and maximum load quantity;
- (b) infectious waste shall be subjected to sufficient temperature, pressure and time to kill *Geobacillus stearothermophilus* spores or induce a complete color change in an approved steam sterilization integrator when either indicator is located in the center of the waste load being decontaminated;
- (c) unless a steam sterilizer is equipped to continuously monitor and generate a printed paper record of time, temperature and pressure during the entire length of each sterilization cycle, a chemical indicator shall be attached to each package of infectious waste that will visually demonstrate at the end of the autoclave cycle that each package was exposed to a temperature of at least 250 degrees fahrenheit or 121 degrees celsius in the presence of steam under pressure was reached during the process; the original printed record generated by the autoclave must be maintained for three years;
- (d) each sterilization unit shall be evaluated for effectiveness with spores of *Geobacillus* stearothermophilus or approved steam sterilization integrator at least once each 40 hours of operation; and
  - (e) a written log shall be maintained for each sterilization unit which contains:
    - (i) date, time and load number for each load;
      - (ii) amount per load;
      - (iii) duration of the cycle; and
      - (iv) the operator's name;
- (3) discharge to a sewage treatment system that provides secondary treatment of waste, if the waste is liquid or semi-solid and approved in writing by the operator of the sewage treatment system; or
  - (4) other products or methods may be approved by order of the secretary which provide:
- (a) a 6Log10 reduction in *mycobacteria* of *Mycobacterium phlei* or *Mycobacterium bovis* (BCG) or if specifically approved, other Mycobacterium species;
- (b) a 4Log10 reduction in bacterial spores of *Geobacillus stearothermophilus*, *Bacillus atrophaeus* or if specifically approved, other species of spore-forming bacterium; and
- (c) verification that the species used in Subparagraphs (a) and (b) of Paragraph (4) of this subsection are the species indicated and that the strain used is appropriate for the proposed method.
- G. The following requirements and condition shall apply to any person seeking approval from the secretary for a treatment method under Paragraph (4) of Subsection F of this section:
- (1) the person shall provide any information requested by the secretary within the time period specified by the secretary;
- (2) the request for approval shall be approved, approved with terms and conditions, or denied by the secretary;
- (3) within 45 days from the end of each calendar year, manufacturers of on-site treatment or processing products approved by the secretary shall submit an annual report to the department that includes:
- (i) current manufacturer's company name, contact names, addresses, and telephone numbers:
- (ii) a current list of product consumers or clients in New Mexico identified as generators of infectious waste under Subsection A of 20.9.8.13 NMAC, with contact names, addresses, and telephone numbers;
- (iii) proof of current registration with the U.S. EPA, if required under the Federal Insecticide, Fungicide, and Rodenticide Act;
  - (iv) a current material safety data sheet for any materials used in the treatment method;
- (v) a current copy of the manufacturer's instructions as printed on the product and a copy of the most recent operator's manual, if not previously submitted; and
- (vi) proof of current registration with the New Mexico department of agriculture, if required under the New Mexico Pesticide Control Act;
- (4) the secretary may withdraw the approval of an on-site processing product if the product fails to properly treat infectious waste as claimed, or if the on-site processing product or method is altered in any manner; to withdraw the approval, the secretary shall issue an order withdrawing the approval; the interested person may appeal

the secretary's order by filing a request for hearing within 30 days of the date of the secretary's order; the procedures set forth in Adjudicatory Procedures - Environment Department, 20.1.5 NMAC shall apply to the appeal.